

State of health, veterinary and biosecurity in Ukraine

Доклад DTRA в рамках Программы совместного биологического взаимодействия по оценке систем здравоохранения и ветеринарии, биобезопасности, связанных с ними процессов и недостатков



Cooperative Biological Engagement Program, Defense Threat Reduction Agency

CBEP Country Assessment: Ukraine



EXECUTIVE SUMMARY

The Biological Engagement Program (CBEP) Ukraine Country Assessment Report is an analysis of the human and animal health systems' structure as well as an surveillance (BSV) and biosecurity (BS&S) infrastructure, processes, assessment provides data for CBEP's short- and long-term strategic plans with programmatic metrics.

A team of interdisciplinary subject matter experts (SME) conducted the assessment of data collection: (1) open-access research, (2) stakeholder telephone (3) in-country validation (interviews and selected site visits). Data from these have been analyzed and organized into human and animal health sections. Each an overview of system governance, national and legislative regulatory get and funding mechanisms, systems priorities, and international standards is followed by a description of Ukraine's capabilities and gaps, aligned to the IV and BS&S metrics pillars: disease detection, laboratory diagnostics, analysis and investigation, reporting and communications, national and networks, facility-level biorisk management systems and culture, and national of security. The final section describes One Health capabilities and gaps. A brief human and animal health sections, as well as a combined overview of BSV and es and gaps, is outlined below.

Ukraine has been moving toward a Western model of governance structures and As a result, both the human and animal health systems have undertaken a series organize central authorities and enhance service provision. However, the country a considerable challenges in this process, including a struggle to overcome Soviet-era ideologies, profound economic issues, and a rigid approach to e there are prominent gaps in the system, often compounded by the challenges opportunities for the Ukrainian government and its supporters to continue the bility and internationally-accepted standards.

Overview

A moderate risk for transboundary incursions of two pathogens of security concern g countries: highly pathogenic avian influenza (HPAI) virus from Poland and cells spp. from Romania and Russia. Endemic pathogens of security concern are us, *Clostridium botulinum*, *Francisella tularensis*, *Bacteroides* spp., *Coxsackie* in Congo hemorrhagic fever (CHF) virus, and tick-borne encephalitis virus. gged by an uneven distribution of healthcare workers, access to primary care, healthcare services. Furthermore, Ukraine has not reported progress toward the organization's (WHO) International Health Regulations 2005 (IHR) [2005]. In the last 5 years, currently, the only IHR core capacity that has been palation related to infectious diseases. In an effort to stimulate effective reforms, tied four priorities for the Ukrainian health system: (1) shifting to a primary care very model that emphasizes preventive care, (2) reallocating financial resources

Level Biorisk Management Systems and Culture

With national regulations is a clear priority for human and animal laboratories and lities, but few facilities take additional measures to align with WHO and EU Facilities document plans and procedures in accordance with national regulations, the proper use of laboratory equipment, but they often neglect biosecurity. Incidents, and subsequent corrective actions are poorly documented and tracked, resulting in records that inhibit the ability to identify and effect necessary improvements. Funding hinder the ability of entities to develop and sustain infrastructure, train BS&S and personnel, procure and properly maintain safety equipment, and provide appropriate effective equipment (PEP). Despite these constraints, the biosecurity culture at it is relatively strong, personnel demonstrate awareness of BS&S and an ng of current policies, procedures, and international regulations

Consolidation and Security

It is identified and consolidated pathogens of security concern into several institutions, per consolidation has encountered resistance from indigenous leadership. Health ms aim to facilitate further consolidation. Ukraine does not have legislation to control of pathogens of security concern, and significant gaps exist in biosecurity Physical security measures at human facilities exist primarily at national institutions are engaged with external stakeholders. However, a lack of adequate funding are has resulted in much of the donated equipment either falling into disrepair or being 'cool' savings. In general, physical security measures at animal facilities are better if their human counterparts. Material control and accountability, personnel security, and security, and information security require significant improvement to secure pathogens, but steady funding sources remain the major constraint in implementing ng such biosecurity measures.

The health concept has limited recognition and understanding in Ukraine. Although human any health professionals are aware of the concept, no legislation or One Health has been established and the concept is not extensively practiced. There is no of notifiable zoonotic diseases or pathogens, the flow of information on zoonotic between sectors is minimal, and defined communication protocols are not in place of a zoonotic outbreak, an ad hoc Anti-Epidemiologic Committee assemblies from members of various government agencies; however, this interagency group does not in trainings or exercises on a routine basis. Without an inclusive One Health ere is no institutional coordination to ensure efficient use of scarce resources and to intersect and interdisciplinary disease prevention and control. However, Ukraine U.S. Global Health Security Agenda in September 2015 in which both S&S/CP and articulate.

National Accreditation Agency of Ukraine

recognition Agency of Ukraine (NAAU) issues ISO 17025 accreditation to qualified laboratories. NAAU is an associate member of the European Cooperation for a cooperating member of the International Laboratory Accreditation Cooperation and Accreditation Forum. Because NAAU is the only agency within the former Soviet but meets all international laboratory standards, it is well-suited to provide its services area in the region, which might enhance Ukraine's capabilities as a regional leader. NAAU's capacities may provide a unique opportunity to improve quality standards in er regional nations.

Security Development

Program for the laboratory network needs enhancement because there is currently indardized laboratory training program in Ukraine. While UCDCM, URAP, gional laboratories under SSES have provided important trainings, lack of id standardization of trainings is a weakness in the system. The PIC intends to dual training program that will include a national training center and international laboratory instruction and field epidemiology training. The program is expected gies for sample collection, packaging, and shipping; BS&S; and SOPs for ng. The training program should also include a laboratory quality management in for laboratory supervisors and leading staff. In addition, there will be a post- in the PIC that will coordinate post-graduate training and continuing gh medical credits, seminars, conferences, and other meetings. National y to conduct specialized technical training in partnership with universities. If the training center and development of national trainings for the subjects, including development of a core curriculum to standardize minimum nning education, will be an important next step in establishing a strong yolk.

Key Resources

Key needs for the laboratory system is to determine accurate resource g effective and efficient the PIC structure and functioning. The current state of e most laboratories poorly equipped to respond effectively to a public health e. The EDP laboratories have the needed equipment for rapid detection of infectious oportunities are underfunded and can neither maintain resident kits nor afford to pment, including biosecurity cabinets (BSC). In addition, the infrastructure of is severely outdated and in an extremely poor condition, which increases the ational safety, and biosecurity risks to the facility and of the pathogens they e. Optimizing the system through consolidating laboratory resources would y of resources and capacities to maintain laboratories, including allocating use outdated facilities.

not equivalent to the U.S. Select Agent program or the CEN and significant gaps exist in all aspects of biosecurity, including ion security, information security, material control and a reliability. Implementation of a biosecurity program designed for ve pathogen security.

Pathogens of Security Concern

Pathogens of security concern are stored at facilities that conduct research and L, LREH, and URAP. Pathogen consolidation has been previously ons with international partners, but competition between institutions to consolidate pathogens to limited facilities. The reorganization of ig of laboratories under the PIC presents an opportunity to the UCDCM, LREH, and URAP will report to the PIC.

Facilities have limited capacity to confirm infectious diseases and send s of EDPs to central laboratories for confirmation. Because clinical testing or referred to other laboratories, samples are not stored in ries, which greatly reduces the number of pathogen collections.

Engaged national- and a select few oblast-level institutions to measures, including security grilles on windows, electronic access t, circuit television (CCTV), volumetric sensors, and intercom s, such as incomplete perimeter fencing, windows without bars, ccess controls, CCTV, and alarm systems, exist at most facilities. e bars on the first floor and sometimes second floor windows, trad ibly left unbarred, which would allow easy access for an intruder. The tems at several facilities were not functioning, and the absence of s a serious vulnerability because many doors to laboratories and e. Lack of maintenance and fluctuations in the power supply e electronic access control systems. Some facilities also hie access control systems, volumetric sensors, CCTV, and alarm consumption because the laboratories are often unable to afford ions at the institutes pose a major challenge for implementing and measures.

Accountability

Large collections of pathogens of security concern, but material g collections are limited. Pathogens are accounted for using files are not always accurately maintained. Freezer equipment for and in danger of failing. At least one facility visited during the appropriate equipment for long-term storage and regularly cultures s. Frequent culturing of pathogens increases access to isolates and trols. Several facilities use wax seals to monitor access to collections related technique. Presently, there is a deployment plan for Pathogen

Entity	Domain	Key projects, milestones and processes of note
Ministry of Health (MHA), State Biosecurity Agency	Human	The Department of External provides strategic planning and analysis of measures and functions of the MHA
Accreditation Agency of Ukraine (NAAU)	Animal /Human	NAAU is the accreditation agency of Ukraine for both human and animal laboratories. Laboratory accreditation issues include ISO 17025
Science, LLC	Animal /Human	Science Solutions supported the ETRB in several human and animal health projects: URAP restoration, laboratory training, management, and emergency response training; and IVM and EUCM physical security and biosecurity assessments.
State Institute of Virology and Technology Center of Ukraine (SVTCU)	Animal /Human	SVTCU is an international government entity, jointly governed by Canada, the U.S., Ukraine, and the United States, that funds and facilitates collaborative reorganization research and activities in Eastern Europe, Central Asia, the United States, and the EIT SVTCU. It was closed back in activities due to political turmoil in Ukraine.
Academy of Postgraduate Studies	Animal /Human	SVTCU is a prominent medical post-graduate medical education and research facility in Kyiv. There are 81 departments in the academy that provide both theoretical and practical trainings to students. According to its local stakeholders, post graduate studies are provided by only three institutions in Ukraine and one.
Soros Foundation	Human	The Soros Foundation has provided tens of millions of dollars to Ukrainian NGOs to assist them in transforming the country into a more "open" and "democratic" society.
Emergency Service of Ukraine (ESU)	Animal /Human	ESU is the central executive body under the Cabinet of Ministers charged with implementing state policy on civil protection, protection of people and territories in emergencies, and prevention and elimination of emergencies. SSES has responded to IPR, influenza, and A&N outbreaks in recent years.
State Institute of Virology and Strains of Infections (SVSI)	Animal /Human	SSES/ISMS serves as the national center for strains of microorganisms in Ukraine, storing and maintaining 700 strains of microorganisms. In addition to scientific research and diagnostic tools development, it serves as the national reference center for rabies.
State Institute of Virology and Strains of Infections (SVSI)	Human	The SSES is the central body responsible for monitoring and controlling disease outbreaks in Ukraine. It prevents and eliminates disease and environmental contamination by improving hygiene and sanitary conditions. In 2011, SSES separated from MHA and became an individual state executive body. Subsequently, SSES was ordered to be liquidated and its functions subsumed under the PRC and S&S/CP.
State Institute of Virology and Strains of Infections (SVSI), State Veterinary Biological Station (SVBS)	Human	SSES are local entities that are responsible for epidemiological and public health interventions during a health crisis. SSES are located in the oblasts and regions. They report disease data to higher administrative levels and conduct investigations and implement control measures during disease outbreaks.
State Institute of Virology and Strains of Infections (SVSI), Oblast Laboratory (OLC)	Human	OLCs are the regional laboratory centers for the EDP laboratory network. In addition to diagnostic testing, they provide oversight and training to region laboratories in their respective oblasts.
State Institute of Virology and Strains of Infections (SVSI), State Veterinary Biological Station (SVBS), and State Veterinary Biological Station (SVBS)	Animal	SSES/DVSE conduct scientific studies of Group I pathogens and serve as the central veterinary laboratory for confirmatory diagnostic testing of samples referred by Regional Diagnostic Veterinary Laboratories (RDVL) and other subnational laboratories.
State Institute of Virology and Strains of Infections (SVSI)	Animal	SVBS is currently an agency under MHA/PA that oversees, regulates, and performs the majority of the animal biosecurity-related activities in the country.
State Institute of Virology and Strains of Infections (SVSI), Regional Laboratory (RL)	Animal	RDVLs are the regional laboratory centers for the EDP animal laboratory network. In addition to diagnostic testing, they provide oversight and training to region laboratories in their respective oblasts.

"...Ukraine has not shown progress in implementing WHO international health regulations (from 2005) for the past five years..."

"...There is no legislation on the control of highly dangerous pathogens and there are significant biosecurity deficiencies..."

"...The current state of resources makes it impossible for laboratories to respond effectively to public health emergencies..."

"...Gross violations, such as unlocked perimeter fencing systems, unattached windows, broken or inactive access control and alarm systems, are common in most institutions..."

"...the Soros Foundation... has contributed to the development of an open and democratic society..."



Pentagon and Bundeswehr study on the spread of highly dangerous pathogens

Project UP-8

Study on the prevalence of Crimean-Congo haemorrhagic fever virus and hantaviruses

Implementation period: 2017-2019

ATM TEXAS A&M UNIVERSITY



Texas A&M University, College Station, USA

Розповсюдження вірусу Крим-Конго геоморфічної групи (вірус ККГГ) і хантавірусів в Україні та потенційна потреба диференційної діагностики у пацієнтів з підозрою на лептоспіроз

2.6.3. **Напрямок до діагностики лептоспірозу.** Лабораторно гострий лептоспіроз людини може бути діагностовано за допомогою ПІР та серологічних досліджень, зареєстрованих ЕІІІА та реакції мікроаглютинації (МАТ) [14, 39]. Однак антиген до антигену різко виявляється методом МАТ у перші сім днів перебігу захворювання, а чутливість зростає значно пізніше від 100%, особливо протягом перших 14 днів захворю [39]. Невисловлено було розроблено чотири типи основи ПІР для виявлення ДНК лептоспір в сечі, що дозволяє діагностувати інфекцію в зразках, отриманих на ранньому етапі перебігу хвороби до того, як з'явиться можливість виявити антиген. Як МАТ, так і ПІР доступні в Україні, і попередні дані в Давно свідчать про те, що лептоспірозо можна підтвердити за допомогою ПІР. МАТ або обох методів приблизно у 90% пацієнтів з клінічними діагнозом гострого лептоспірозу (Зубен О., особисте спілкування).

III. ПЛАН ДОСЛІДЖЕННЯ

3.1. Цілі

3.1.1. Основні цілі:

1. Вивчати серопревалентність антитіл до хантавірусів серед 4000 і вірусу ККГГ серед 400 зареєстрованих добровільців, залучених установами військових частин та медичних академії Міністерства оборони України, розташованих у Львові, Харкові, Одесі та Києві, і порівняти ці дані з інформацією у їх медичних картках, розроблених анкетах.

Захворювання, викликані хантавірусами, були вперше виявлені під час Корейської війни, коли близько 1500 військовослужбовців ООН захворіли на певному фідельному хворобу з ознаками ураження нервової та серцево-судинної систем. Як доказали результати досліджень за період багатьох років, військова діяльність (ритм освіти, земельні роботи в полі) призводять до високої ризику для солдатів, які були-вони інші види діяльності. Таким чином, ця популяція може протити сьвідо на поширеність хантавірусів у навіоціоні середовища та потенціал виникнення захворювання, особливо Мінсборони має військові частини на всій території країни. Окремі збір зразків МОЗ локалізований у двох областях з метою забезпечення інформаційних оціночних даних про інтенсивність захворювання, у той же час, за результатами діяльності Мінсборони будуть отримані оціночні дані щодо рівня інфікування з'єднаннями ККГГ та ГГІС в Україні. Ці дані також будуть використані на запитання про те, чи естрація даних про уривки та клініч на національний рівень може надати цінну військову інформацію.

2. Ідентифікувати антитіла до вірусу ККГГ та хантавірусів у сироватках крові людей виворочувачи шийний підста до виборки зразків добровільців.

14

бувають вилучені з аналізу та знищені.

3.5. Протоколи на випадок відхилення від протоколу

Весь медичний персонал, що проводить набір зразків крові та персонал лабораторій Служби превентивної медицини МО України, який бере участь у лабораторному процесі, до початку дослідження проходить навчання з протоколу та етапів проведення досліджень, суб'єктом якого є людина. У разі невиконання вказаних осіб, що не відповідають критеріям вказаним, біологічні зразки від них не повинні збиратися, будь-які збори мають бути вилучені з аналізу та знищені, а особа має бути проінформована про це. Якщо транзит для лабораторних досліджень від осіб, що не відповідають критеріям вказаним, має бути відібраний, вони будуть вилучені, а особа – проінформована про це.

У випадку, про відхилення від протоколу, що не впливають на зарозум'я учасників, буде повідомлено під час поточного перегляду протоколу та або в остаточному звіті. Про відхилення від протоколу або неочікувані ситуації, що можуть вплинути на зарозум'я, безпеку або благополуччя учасників дослідження, буде негайно повідомлено головному досліднику / менеджерові і збори даних, чарльсьому комітету з біобезпеки та Атентсуп (вирешення маргом Міністерства оборони США (A33). Про неочікувані випадки слід повідомити протягом 72 годин, а про серйозні, пов'язані випадки смерті – протягом 24 годин. Усі випадки смерті суб'єкту дослідження, пов'язані з участю в дослідженні, так само повідомляти з процесурними дослідженнями, повинні бути доведені до відома комітету із біобезпеки в США та Україні. Про будь-які відхилення від протоколу або неочікувані ситуації, які викликають занепокоєння щодо наукової об'єктивності дослідження, також буде негайно повідомлено головному досліднику, головному співдосліднику, українському комітету з біобезпеки та А33.

Якщо очікується відхилення від протоколу, головний дослідник та головний співдослідник повідомлять комітет з біобезпеки в Україні, а також зазначать зарозум'я довіри на вивіток з протоколу з А33. Усі зміни в протоколі та згоди повинні бути схвалені комітетами з біобезпеки в Україні до початку їх впровадження.

UP-8 research programme

Project 68727 EN 02761868

Study of Congo-Crimean haemorrhagic fever pathogens and hantaviruses

Implementation period: 2018–2019



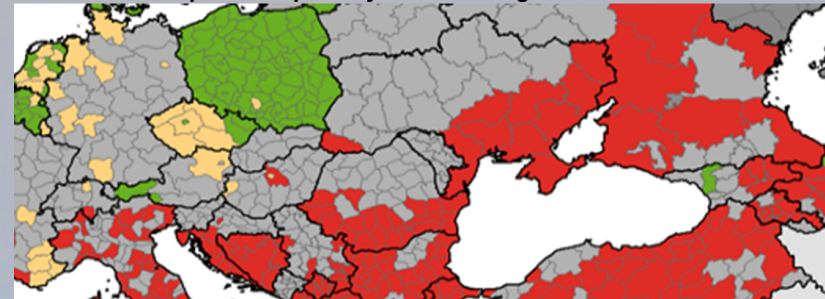
Institut für Mikrobiologie der Bundeswehr

Institute for the Microbiology of the Armed Forces of the Federal Republic of Germany

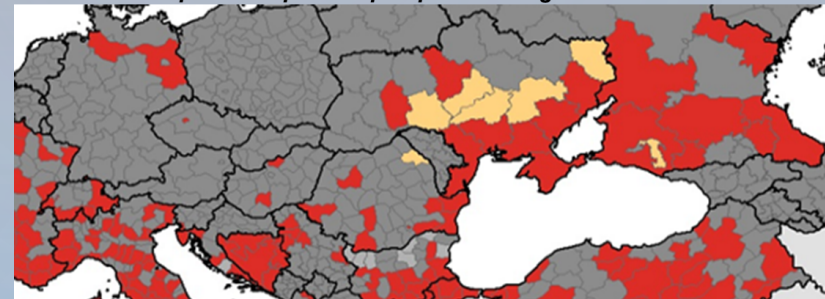


Tick spread areas

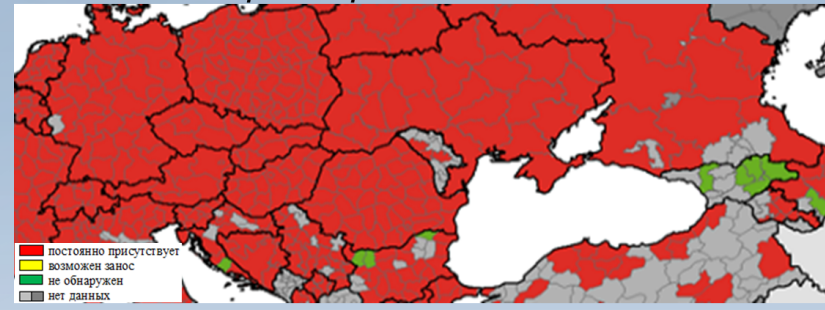
Spread map of Hyalomma marginatum ticks



Spread map of Rhipicephalus sanguineus ticks



Spread map of Ixodes ricinus ticks



Legend for tick spread maps:
- Red: постоянно присутствует (permanently present)
- Yellow: возможен заход (possible entry)
- Green: не обнаружен (not detected)
- Grey: нет данных (no data)



Ukrainian projects to study economically significant infectious diseases

TO1 Veterinary TAP-3

Analysis of the risks of spreading African swine fever and swine flu virus among wild pigs in Ukraine

TO4 Veterinary TAP-6

Risk analysis of the spread of African swine fever virus in wildlife in Ukraine: improving diagnosis, detection and prevention



Employees of the Institute for New Pathogens at the University of Florida studied wild boar populations in Volyn, Rovnoe, Zhitomir and Chernigov regions of Ukraine and in the areas bordering Russia and Belarus

UF UNIVERSITY OF FLORIDA



University of Florida (Gainesville, USA)

Epizootic situation of African swine fever in 2007-2022



Biological Threat Reduction Programme Summary Report for Ukraine (27.06.2019)

BUILDING A WORLD OF DIFFERENCE™

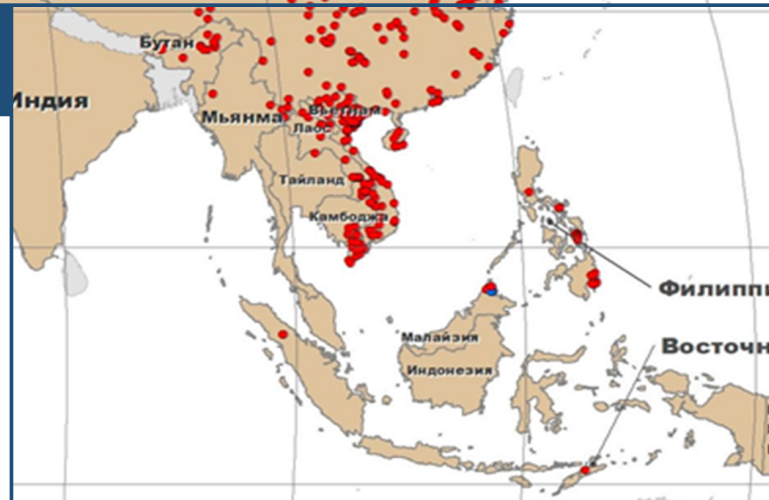
Biological Threat Reduction Program (BTRP)

Program (BTRP) Phase IIb
HDTA1-05-D-0007-0004
CDRL A017
Country Science Plan (CSP)

Presented by:
BLACK & VEATCH SPECIAL PRODUCTS CORP.
In collaboration with Metabio, Inc.
METABIO
Rev. 06
Submitted 27 June 2019

Table 2. Task Status

Project Designation	Project Title	Approved	On Track	Delayed	Not Started
TO1 Veterinary TAP-3	Investigation of Cell Culture and Related Assay Sequencing Capabilities at the Diagnostic Research and Reference Level (DRRL) to Enhance Faster and Improve Viral Diagnostic	✓	✓		
TO1 Veterinary TAP-4	Development and Use of a Reverse Transcriptase for Avian Influenza Virus (AIV) Diagnostic Based on Reverse Transcriptase from Avian Influenza Virus (AIV)	✓	✓		
TO1 Veterinary TAP-5	Analysis of the Threat of Spread of African Swine Fever Virus (ASFV) from Eastern Europe (EE) to Western Europe (WE)	✓	✓		
TO1 Veterinary TAP-6	Validation of the Detection of Highly Pathogenic Avian Influenza Virus (HPAIV) and Virulent Newcastle Disease Virus (VNDV) Based on Virus	✓	✓		
TO1 Veterinary TAP-7	Biological Monitoring of Swine in Ukraine and Evaluation of Alternative Methods for Laboratory Diagnosis of ASFV	✓	✓		
TO1 Veterinary TAP-8	Analysis and Review of Ukrainian Legislation and Guidelines for Veterinary Laboratory Diagnostic Quality Assurance, Biological Safety, and Biological Security for Swine (BSS), with the Aim of Identifying Potential Vulnerabilities to the Veterinary System	✓	✓		
TO1 Veterinary TAP-9	Continuing Research to Support Understanding of ASF Entry and Epidemiology in Eastern Europe: Training and Experience for Methods and Strategies for Control and Prevention	✓	✓		
TO1 Veterinary TAP-10	Continuing Research to Support Understanding of ASF Entry and Epidemiology in Eastern Europe: Training and Experience for Methods and Strategies for Control and Prevention	✓	✓		
TO1 Veterinary TAP-11	Analysis of the Threat of Spread of African Swine Fever Virus (ASFV) from Eastern Europe (EE) to Western Europe (WE) and Clinical Swine Fever in Wild Boar Populations in Ukraine: Improved Diagnostic, Surveillance, and Prevention	✓	✓		





Results of blood samples from Ukrainian POWs



US Department of Defense Threat Reduction Agency (DTRA)



Black&Veatch Special Projects Corp.



Ukrainian Ministry of Defence

UP-8 Project

Crimean-Congo haemorrhagic fever virus and hantavirus prevalence study in Ukraine (2017-2020)

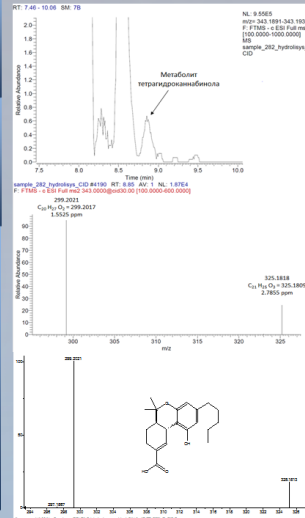
\$ 1,658,236

Number of sick and previously outnumbered Ukrainian military personnel:

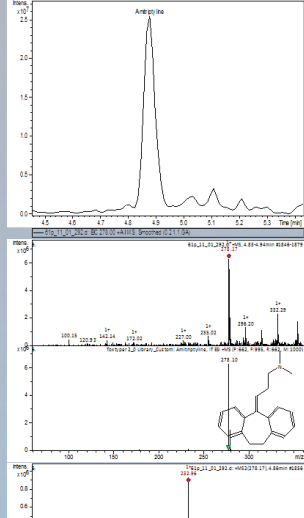
- fever with kidney syndrome — **4** %
- West Nile fever — **20** %
- hepatitis A — **33** %

Analysis of samples revealed traces of narcotics, stimulants, antibiotics

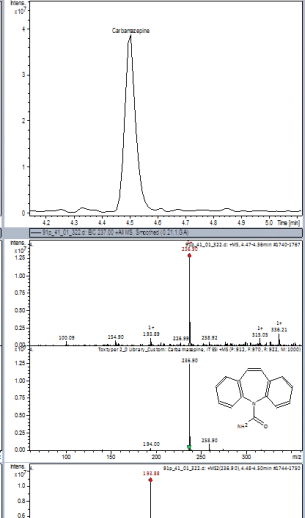
Metabolite of tetrahydrocannabinol



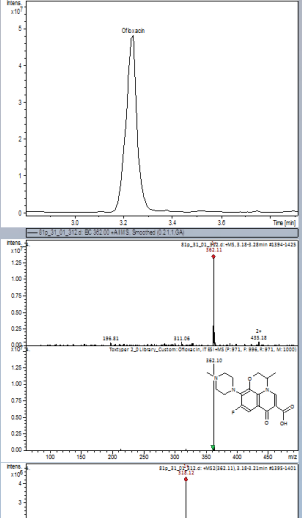
Amitriptyline



Carbamazepine



Oxofloxacin



Sulfadimethoxine

