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Research Article,

A Nano Botanical Composition for Treatment of HIV/AIDS Virus

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Abstract:

The present invention relates to a Nano pharmaceutical immunity enhancer antiviral composition for treatment of HIV/AIDS. The composition (IMUTECH) for treating HIV/AIDS, preferably formed of Nano herbal extracts, contains Aloe Vera, Ganoderma, Mushroom, Harmala, Andrographis, Wormwood and Black Seed or extracts of them. In particular the composition is given to all types of cancer to increase immunity and to enhance the treatment of HIV/AIDS. Observed results showed excellent results in 15 years for HIV/AIDS with no adverse or side effects

Background of the invention:

According to World Health Organization (WHO) in a report issued in 2018(1)

Global situation and trends:

Since the beginning of the epidemic, 75 million people have been infected with the HIV virus and about 32 million people have died of HIV. Globally, 37.9 million [32.7–44.0 million] people were living with HIV at the end of 2018. An estimated 0.8% [0.6-0.9%] of adults aged 15–49 years worldwide is living with HIV, although the burden of the epidemic continues to vary considerably between countries and regions. The WHO African region remains most severely affected, with nearly 1 in every 25 adults (3.9%) living with HIV and accounting for more than two-thirds of the people living with HIV worldwide. People died due to HIV worldwide in 2018 were 770,000.

Antiretroviral therapy (ART) coverage among all age groups:

By end 2018, 23.3 million people were receiving antiretroviral treatment.

Situation:

In December 2018, an estimated 23.3 million people globally were receiving antiretroviral therapy. This represented an increase of 2.0 million people over the number receiving such treatment 12 months earlier. Of all persons living with HIV 62% [47-74%] had obtained antiretroviral therapy in 2018. In the WHO African Region, 64% [48-76%] of people living with HIV were able to access life-saving medicines in 2018. Similarly, 67% [49-82%] in the Region of the Americas, 53% [39-71%] in the South-East Asia Region, 55%

[43-64%] in the European Region, 21% [13-31%], in the Eastern Mediterranean Region, and 59% [47-69%] in the Western Pacific Region were accessing such treatment. WHO recommends that everyone infected with HIV needs treatment, better known as the "treat all" recommendation. With an estimated 37.9 million [32.7-44.0 million] million people now living with HIV globally, this represents a significant need to scale up HIV testing and treatment, while continuing to invest in prevention and other programmers to combat new infections. Overall antiretroviral therapy coverage among children was lower than among adults. Children represented 4% of the people receiving antiretroviral therapy and also approximately 5% of the people living with HIV. Of the 1.7 million [1.3-2.2 million] children estimated live with HIV, 54% [37-73%] had access to treatment versus 62% [47-75%] of adults.

Trends:

Access to ART has increased rapidly since 2005 from just 2.0 million to 23.3 million by the end of 2018. The estimated ART global coverage increased from 7% in 2005 to 62% in 2018. The greatest increase occurred in WHO African Region, where ART was uncommon up to 2005 (739 000 people on ART) and increased to 16.3 million in 2018. Regions that have made less progress are those in which the epidemic is predominantly concentrated in populations with lower access and utilization of services, such as sex workers, injecting drug users, and men who have sex with men.

Side effects from antiretroviral drugs can include:

- Hypersensitivity or allergic reactions, with symptoms such as fever, nausea, and vomiting.
- Appetite loss.
- Fatigue.
- Mood changes, including depression and anxiety.
- Trouble sleeping.
- High Lipid; cholesterol and triglycerides.
- Rash.
- Diarrhea.
- Bleeding.
- Bone loss.
- Heart disease.
- High blood sugar and diabetes.
- Lactic acidosis (high lactic acid levels in the blood).
- Kidney, liver, or pancreas damage.
- Bad and bitter experience of chemical drugs and painful side effects lead us to formulate a safe and effective natural alternative 15 years ago which we called IMUTECH; which stands for Immunity Technology.

Using compositions including immunity enhancer extracts; such as Aloe Vera, Ganoderma Mushroom, Harmala Extract, and orography's, Wormwood and Black Seed. It relates to the field of therapeutic natural

products, particularly to plant extracts effective in treating and preventing HIV/AID Sand/or conditions associated there with.

Objects of the invention:

Primary object of the present invention is to provide a composition to enhance immunity and fights viruses. Another object of the present invention is to provide a process for the preparation of the herbal composition for treating HIV/AIDS.

Summary of the invention:

The present invention relates to an oral pharmaceutical composition for treatment of cancer. The composition for treating HIV/AIDS, preferably formed of Aloe Vera, Ganoderma, Mushroom, Harmala, and orography's, Wormwood and Black Seed or extracts of them

Detailed description of the invention:

Present invention relates to the use of a composition which can be formed as an efficient tool to enhance immunity and treat HIV/AIDS virus. The composition of IMUTECH is formed of

Aloe Vera Extract:

In 2012,Oladele S. Olatunya et al(3) used 30-40ml aloe Vera gruel on ten (10) young women diagnosed with human immunodeficiency virus (HIV) infection in the Wesley Guild Hospital Ilesa, a unit of Obafemi Awolowo University Teaching Hospital, Ile Ife, Osun State, Nigeria who did not meet the national criteria for the use of antiretroviral drugs.Their CD4 counts, general improvement, and physical well-being (including weight gain) were monitored over a 1-year period. The findings were compared with those of 20 age- matched controls who were on antiretroviral drugs. One (1) patient who reacted badly to antiretroviral drug switched over to aloe Vera. The researchers concluded that preliminary data the obtained suggest that consumption of aloe Vera may be of help to HIV-infected individuals in the tropics, given its availability and inexpensiveness.

Reishi Mushroom Extract:

A highly oxygenated triterpene named ganoderic acid α has been isolated from a methanol extract of Reishi Mushroom together with twelve known compounds by Sahar El-Mekkawyet al(4) .The structures of the isolated compounds were determined by spectroscopic means including 2D-NMR. Ganoderiol F and ganodermanontriol were found to be active as anti-HIV-1 agents with an inhibitory concentration of 7.8 μg ml^{-1}

Harmala Seed Extract:

A novel antifungal protein, designated as PHP, was isolated from the seeds of Peganum harmala, by Xiaojin Ma et al (5). PHP exerted antifungal activity against Alternaria alternate, Penicillium degitatum, Rhizopus stuolonifer, and Magna porthegrisea. PHP was also able to inhibit the proliferation of esophagus carcinoma (Eca-109), cervical carcinoma (HeLa), gastric carcinoma (MGC-7), and melanoma (B16). Moreover, PHP significantly inhibited HIV-1 reverse transcriptase (RT). The researchers concluded that harmala seed extract possess, a novel antifungal protein with anti-proliferation and anti-HIV-1 RT activities.

Wormwood (ArtimisiaAnnua) Extract:

Artemisinin is a chemical compound extracted from the wormwood plant, Artemisia annua L. It is wellknownthat A.annua is currently mainly being used for the treatment of malaria but also for the treatment of skin and digestion ailments, HIV-AIDS, bronchitis, cancer and hemorrhoids. In vitro activity (6): Information regarding the in vitro anti-HIV activity of A. annual and artemisinin is rather limited. Chang and Woo (2003) tested the methanolic extracts of 80 commonly used Korean medicinal plants against HIV in relation to virus-cell fusion inhibition. They used the syncytium inhibition assay, which is based on the interaction between the HIV-1 envelope and the cellular membrane protein CD4 on T-lymphocytes. In reality, organic extracts are not used, but rather a tea infusion is brewed and administered. Various patents exist that cover the broad biological activity including the antiviral activity of A. annual in combination with other medicinal herbs (Zhang and Zhang 2010; Chen 2010; Nagaura 2009; Xue 2008a, b; Zhang 2003; and Chen 2007).

Black Seed Extract:

Nigella sativa had been documented to possess many therapeutic functions in medicine but the least expected is sero-reversion in HIV infection which is very rare despite extensive therapy with highly active anti-retroviral therapy (HAART). This case presentation (7) is to highlight the complete recovery and sero-reversion of adult HIV patient after treatment with Nigella sativa concoction for the period of six months. The patient presented to the herbal therapist with history of chronic fever, diarrhea, weight loss and multiple popular pruritic lesions of 3 months duration. Examination revealed moderate weight loss, and the laboratory tests confirmed sero-positivity to HIV infection with pre-treatment viral (HIV-RNA) load and CD4 count of 27,000 copies/ml and CD4 count of 250 cells/ mm^3 respectively. The patient was commenced on Nigella sativa concoction 10mls twice daily for 6 months. He was contacted daily to monitor side-effects and drug efficacy. Fever, diarrhea and multiple pruritic lesions disappeared on 5th, 7th and 20th day respectively on Nigella sativa therapy. The CD4 count decreased to 160 cells/ mm^3 despite significant reduction in viral load (≤1000 copies/ml) on 30th day on N. sativa. Repeated EIA and Western blot tests on 187th day on Nigella sativa therapy was sero-negative. The post therapy CD4 count was 650cells/ mm3 with undetectable viral (HIV-RNA) load. Several repeats of the HIV tests remained sero negative, aviraemia and normal CD4 count since 24 months without herbal therapy. This case report reflects the fact that there are possible therapeutic agents in Nigella sativa that may effectively control HIV infection.

Andrographis Extract:

A series of Andro derivatives were described and evaluated (8) for their anti-HIV activity in vitro. Compound **10** and **16b**, of which TI were >10, had anti-HIV-1 activity in vitro. Therein, compound **10** which was the best potent compound, could serve as a new lead for further development of anti-AIDS agents**.**

Examples of pre-clinical results:

12 HIV/AIDS patients took natural IMUTECH 4x3 capsules per day for 2 weeks under the supervision of their medical doctors at the Sudanese AIDS National Center in 2005.Before treatment their viral loads count was in millions of HIV viruses with very low immunity .

After 2 weeks of treatment viral load became zero for all of patients and CD4 immune cells became normal.Sample results are shown below.

After 15 years all patients live good life with zero count of viruses and normal CD4

Safety and toxicity study:

Toxicity study performed on mice in the animal house in Jordan University of Science and Technology showed that the composition is free of adverse effects especially on liver, kidneys, lipid and other body organs.

Conclusion:

This patent-pending botanical formulation is expected to help millions of HIV/AIDS cases worldwide. Double blind is still needed to give more reliable results.

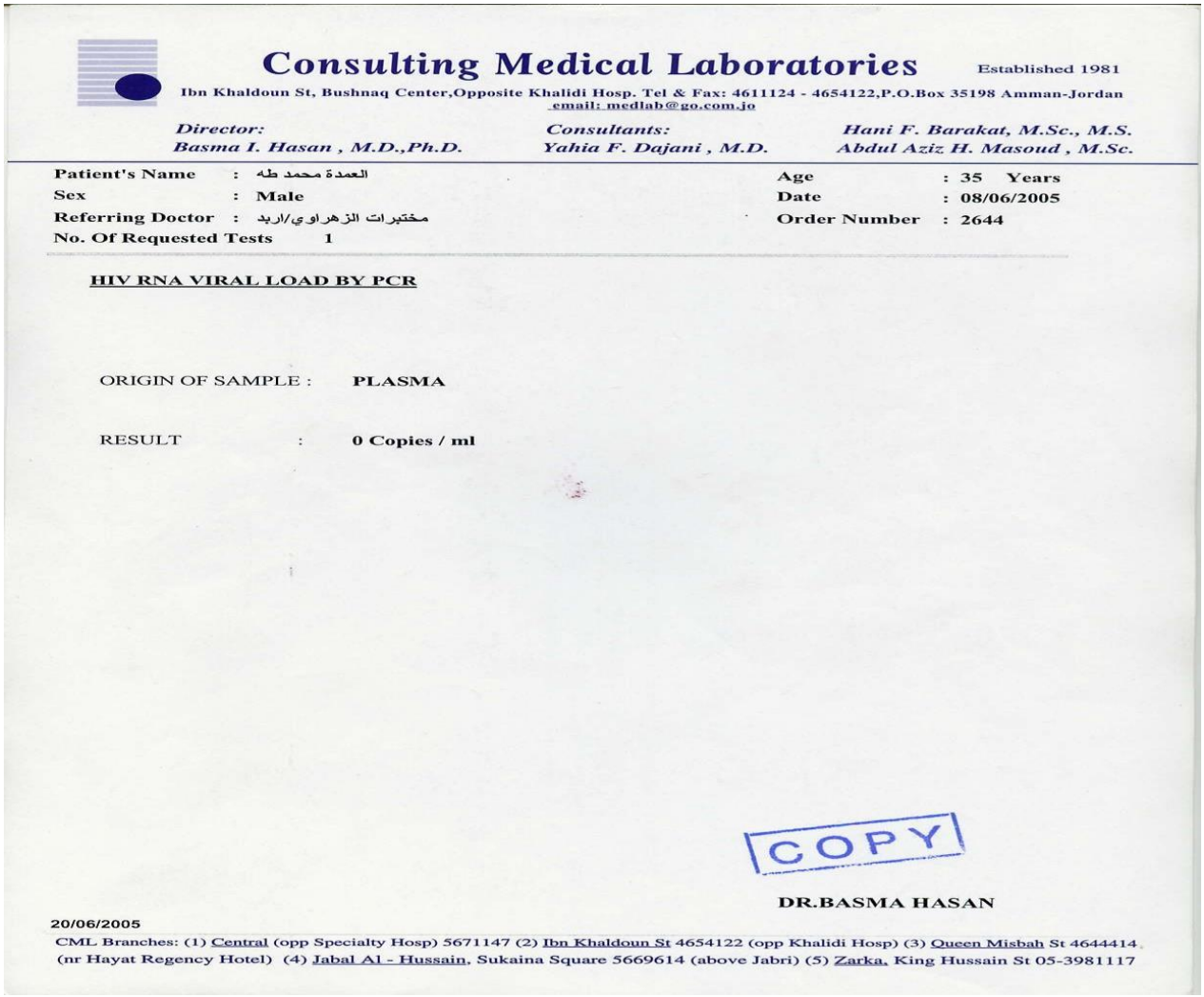
Acknowledgment:

None.

Conflict of interest:

The authors declare no conflict of interest.

Lab Clinical Results:



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Consultants: *Yahia F. Dajani , M.D.*
Hani F. Barakat, M.Sc., M.S.
Abdul Aziz H. Masoud , M.Sc.

Patient's Name : العمدة محمد طه
Sex : Male
Referring Doctor : مختبرات الزهراوي/اربد
No. Of Requested Tests 1
Age : 35 Years
Date : 08/06/2005
Order Number : 2644

HIV RNA VIRAL LOAD BY PCR

ORIGIN OF SAMPLE : PLASMA

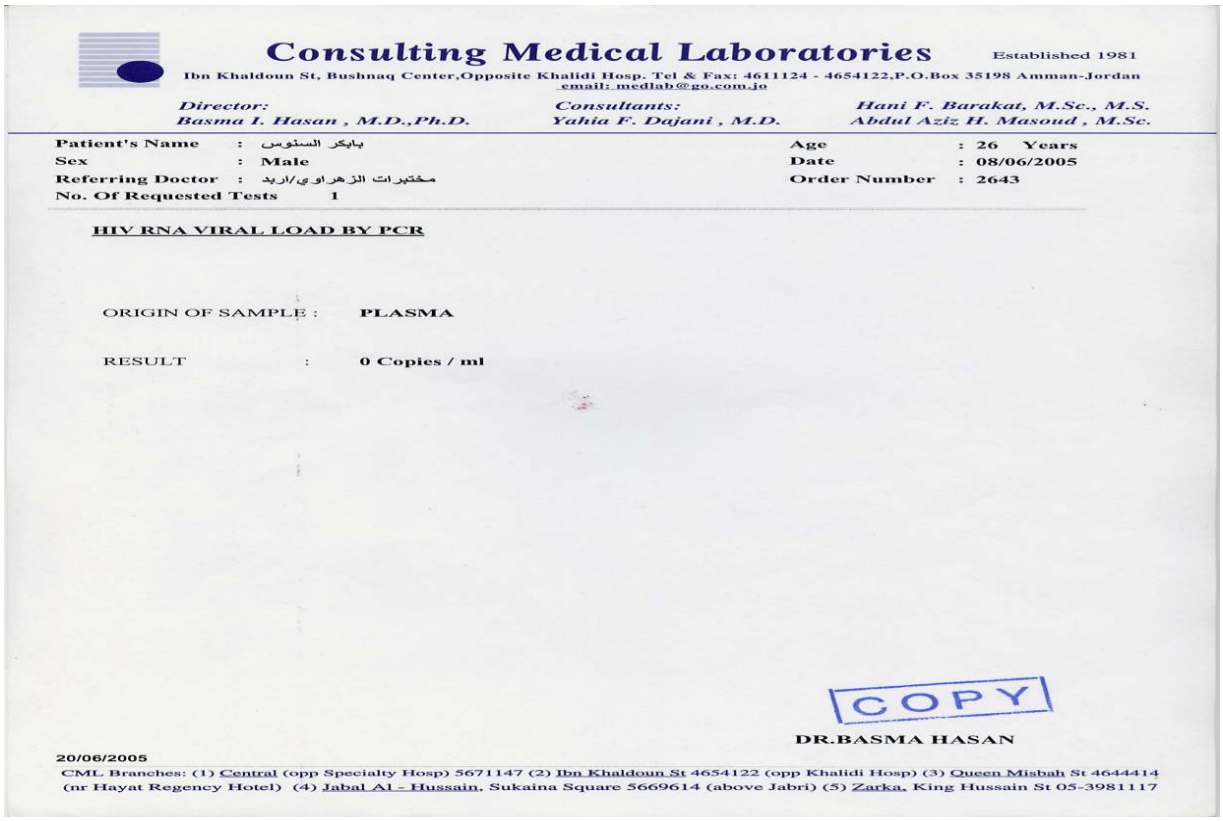
RESULT : 0 Copies / ml

COPY

DR.BASMA HASAN

20/06/2005

CML Branches: (1) Central (opp Specialty Hosp) 5671147 (2) Ibn Khaldoun St 4654122 (opp Khalidi Hosp) (3) Queen Misbah St 4644414 (nr Hayat Regency Hotel) (4) Jabal Al - Hussain, Sukaina Square 5669614 (above Jabri) (5) Zarka, King Hussain St 05-3981117



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email: medlab@go.com.jo

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Patient's Name : بايكر السنوس
Sex : Male
Referring Doctor : مختبرات الزهراوي/اربد
No. Of Requested Tests 1

Age : 26 Years
Date : 08/06/2005
Order Number : 2643

HIV RNA VIRAL LOAD BY PCR

ORIGIN OF SAMPLE : PLASMA

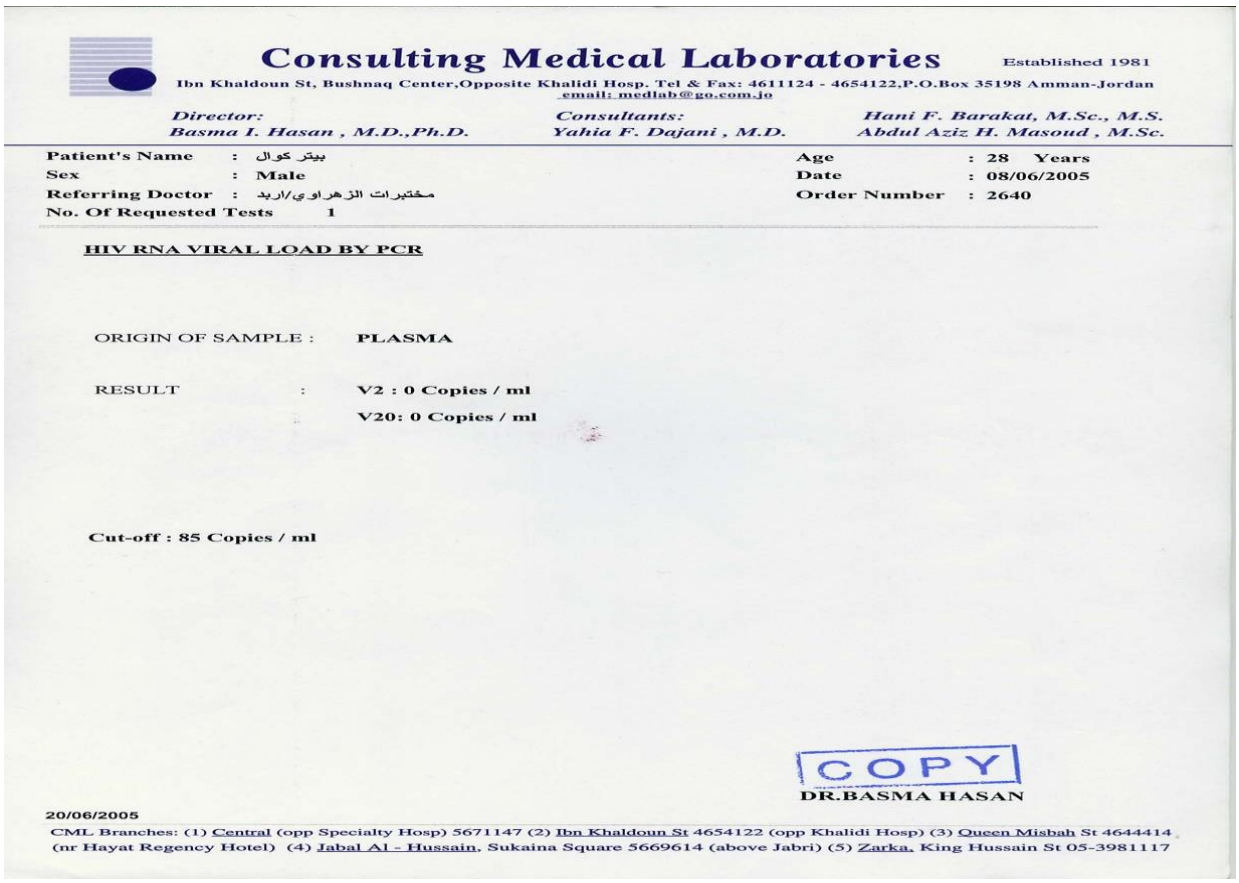
RESULT : 0 Copies / ml

COPY

DR.BASMA HASAN

20/06/2005

CML Branches: (1) Central (opp Specialty Hosp) 5671147 (2) Ibn Khaldoun St 4654122 (opp Khalidi Hosp) (3) Queen Misbah St 4644414 (nr Hayat Regency Hotel) (4) Jabal Al - Hussain, Sukaina Square 5669614 (above Jabri) (5) Zarka, King Hussain St 05-3981117



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Patient's Name : بيتر كوال
Sex : Male
Referring Doctor : مختبرات الزهراوي/اربد
No. Of Requested Tests 1

Age : 28 Years
Date : 08/06/2005
Order Number : 2640

HIV RNA VIRAL LOAD BY PCR

ORIGIN OF SAMPLE : PLASMA

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V20: 0 Copies / ml

Cut-off : 85 Copies / ml

COPY

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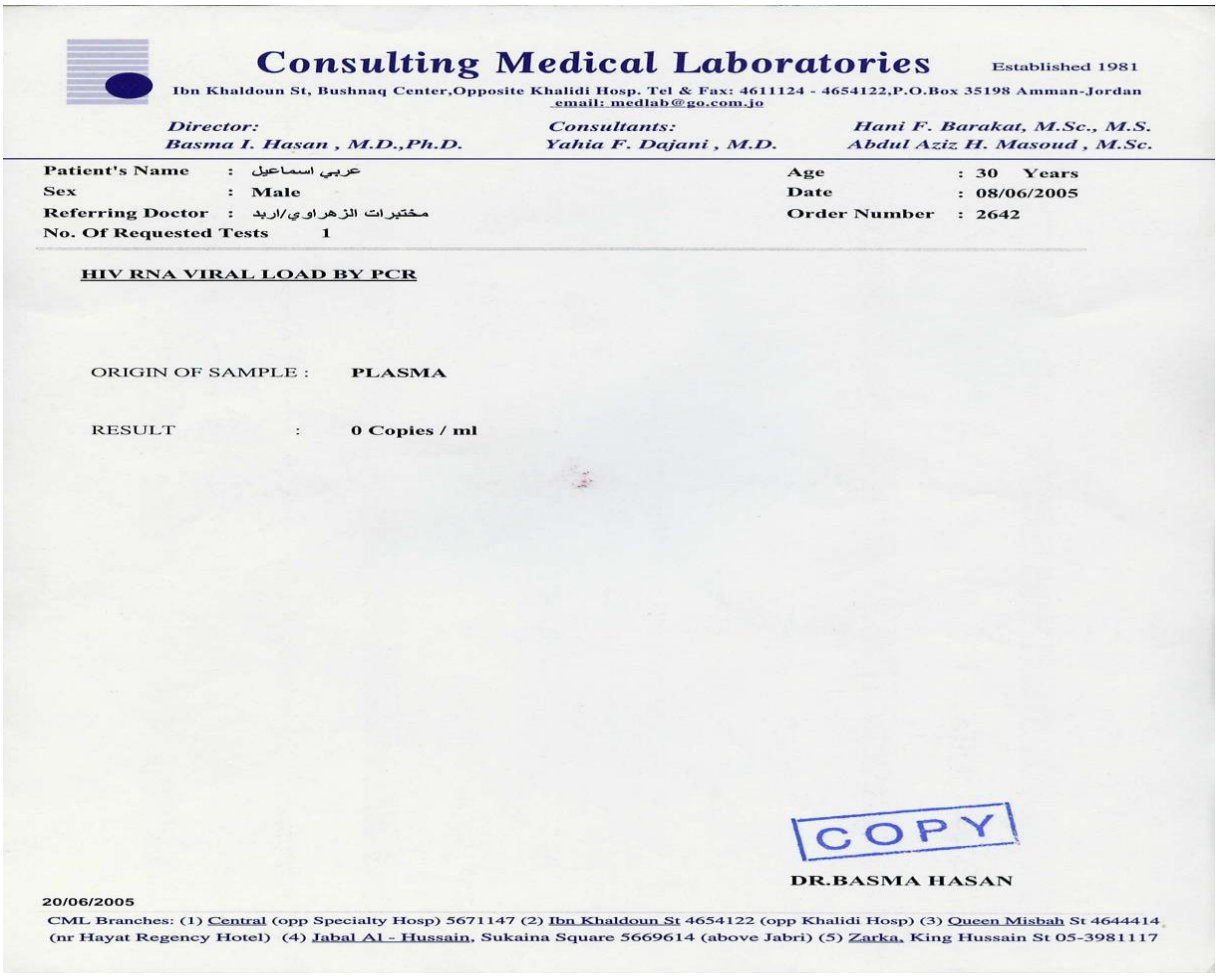

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email: medlab@go.com.jo

Director: Basma I. Hasan , M.D.,Ph.D. *Consultants:* Yahia F. Dajani , M.D. Hani F. Barakat, M.Sc., M.S. Abdul Aziz H. Masoud , M.Sc.

Patient's Name : عربي اسماعيل Age : 30 Years
Sex : Male Date : 08/06/2005
Referring Doctor : مختبرات الزهراوي/اربد Order Number : 2642
No. Of Requested Tests 1

HIV RNA VIRAL LOAD BY PCR

ORIGIN OF SAMPLE : **PLASMA**

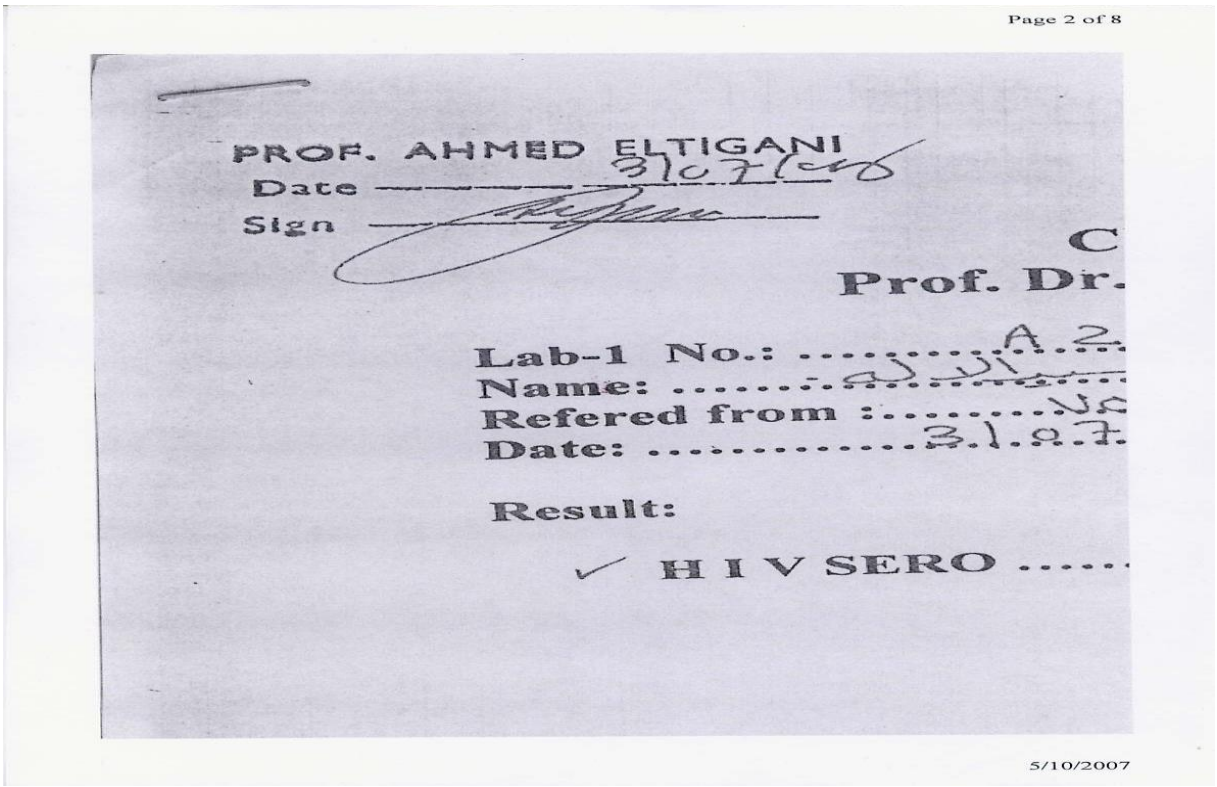
RESULT : **0 Copies / ml**

COPY

DR.BASMA HASAN

20/06/2005

CML Branches: (1) Central (opp Specialty Hosp) 5671147 (2) Ibn Khaldoun St 4654122 (opp Khalidi Hosp) (3) Queen Misbah St 4644414 (nr Hayat Regency Hotel) (4) Jabal Al - Hussain, Sukaina Square 5669614 (above Jabri) (5) Zarka, King Hussain St 05-3981117



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PROF. AHMED ELTIGANI
Date 31.7.06
Sign

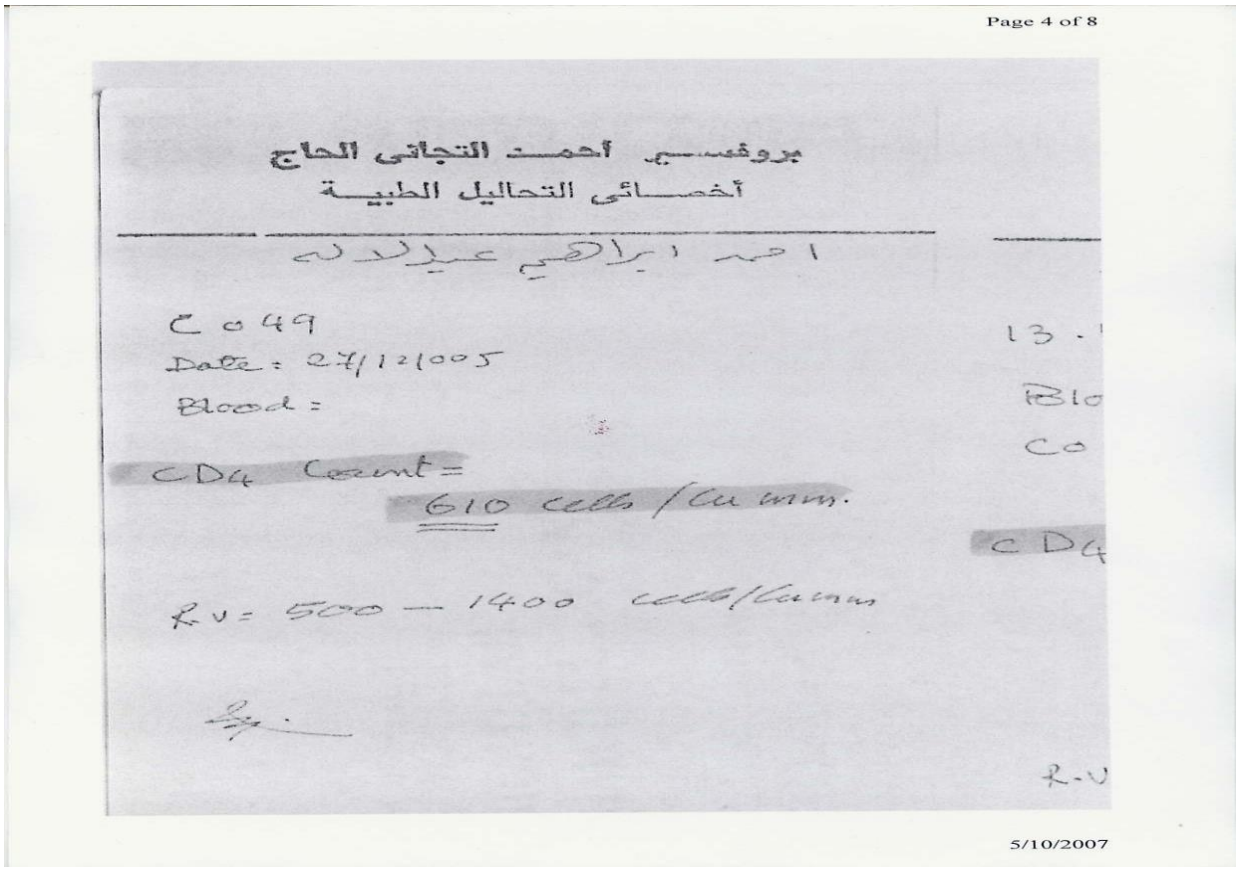
Prof. Dr.

Lab-1 No.: A.2.
Name:
Refered from :
Date: 31.9.7.

Result:

✓ H I V SERO .....

5/10/2007



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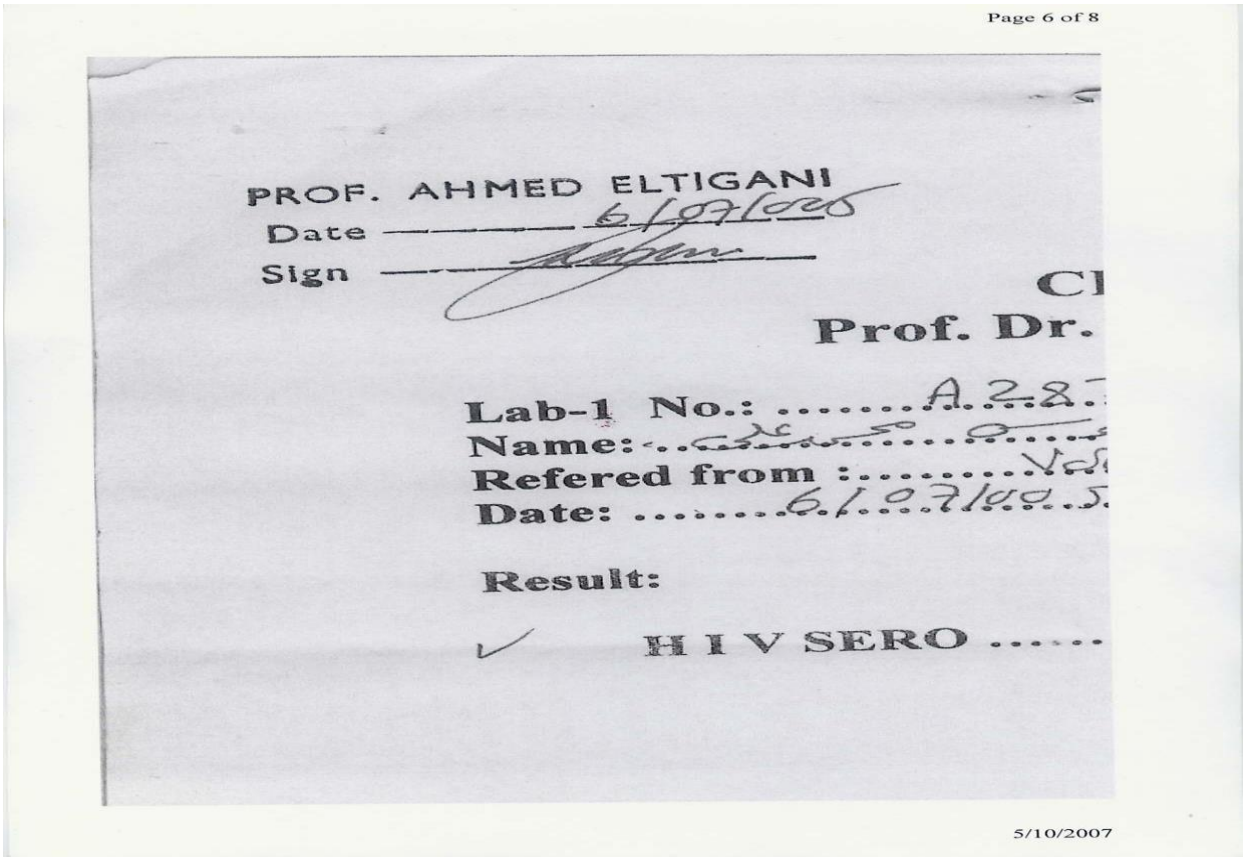
بروفسير أحمد التجاني الحاج
أخصائي التحاليل الطبية

احمد ابراهيم عبدالله

C o 49
Date: 27/12/2005
Blood:
CD4 Count =
610 cells/cu mm.
R V = 500 — 1400 cells/cumm

13.
Blo
Co
cD4
R.V

5/10/2007



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PROF. AHMED ELTIGANI
Date 6/12/2005
Sign

Cl
Prof. Dr.

Lab-1 No.: A.2.8.
Name:
Refered from :
Date: 6.12.2005

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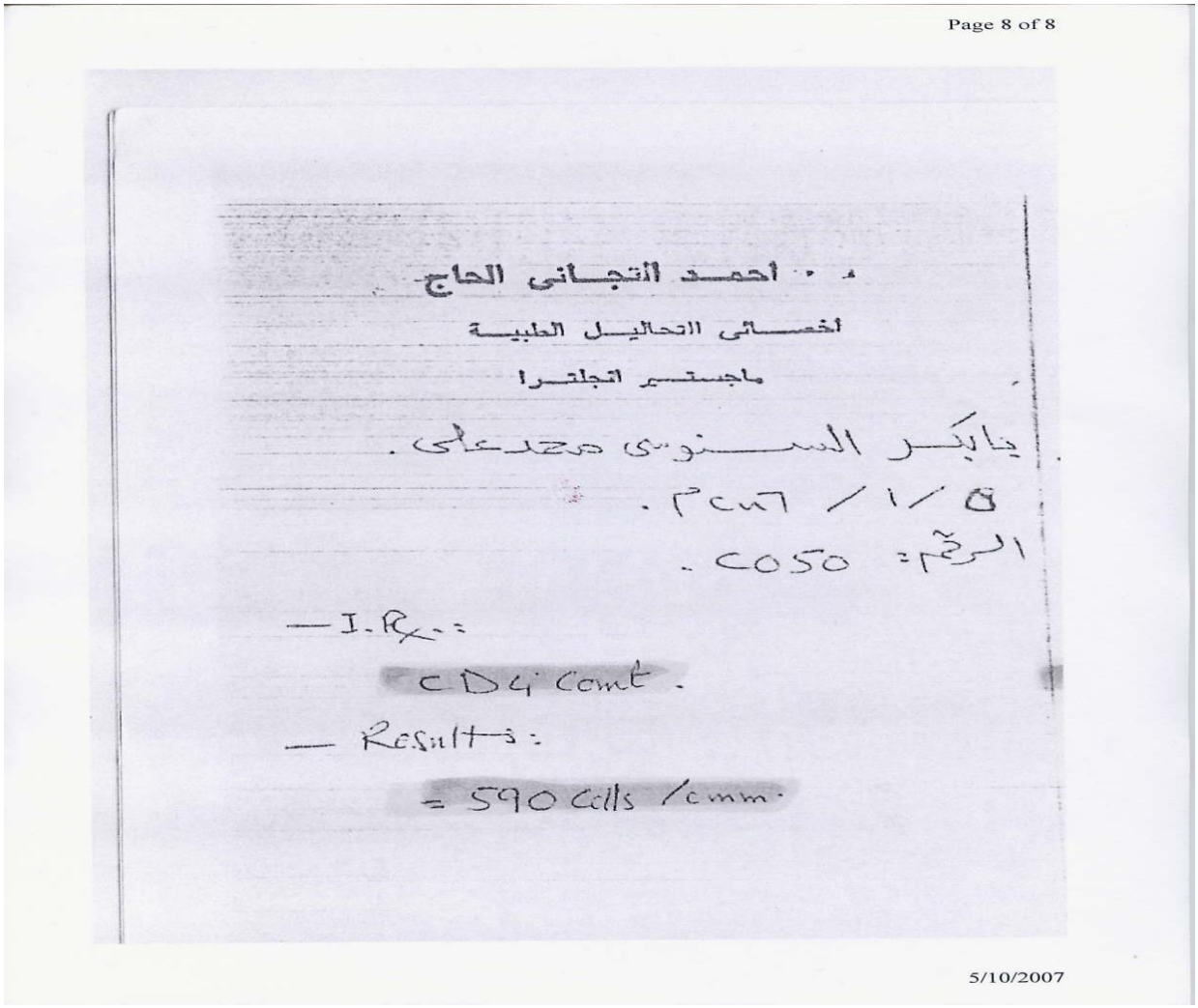
5/10/2007



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