Bridging Gaps Towards Blood Safety
NBTS Experience In NAT Screening

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Director General of National Blood Transfusion Services
Egypt

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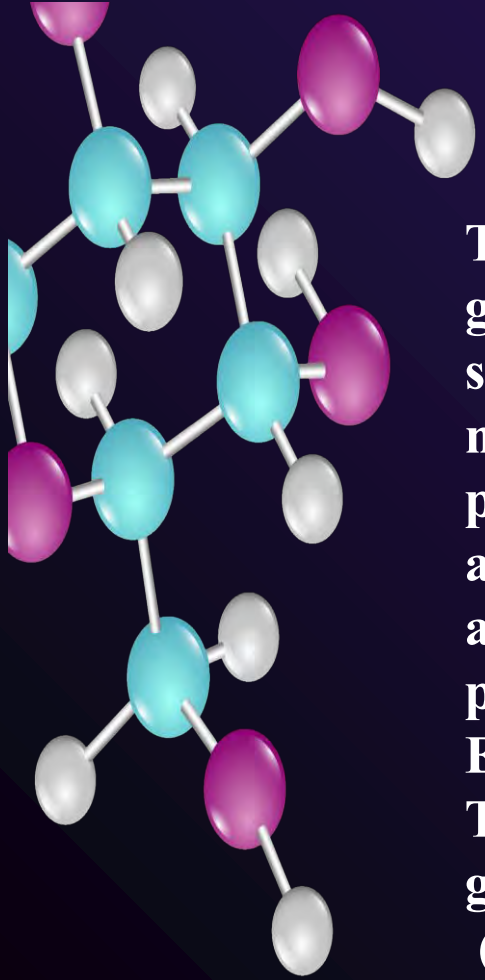

INTRODUCTION

The National Blood Transfusion Service (NBTS) is a governmental non-profit health organization that provides safe, effective blood and blood products through a voluntary non-remunerated blood donation. (NBTS) started as a joined project between Egypt represented by the ministry of health and Switzerland represented by the red cross . The project aimed to develop the whole blood transfusion system and provide a safe effective blood and blood components all over Egypt.

The (NBTS) is a network of 28 centres all over Egypt in 27 governorates with the national blood transfusion center (NBTC) as headquarter .

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ACCREDITATION

- NBTC has been accredited by the Association for the Advancement of Blood & Biotherapies (aa bb) 4 Times.
- 4TH accreditation round was in Dec.2022 .

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RCRL NBTC has been accredited by EGAC in compliance with the requirement of ISO 15189:2012

EGAC

ilac-MRA

Accreditation Certificate No. (052318A)

Arab Republic of Egypt

Egyptian Accreditation Council (EGAC)

Certifies that

Red Cells Reference Laboratory

National Blood Transfusion Services

(51) Wezaret El Zeraa Street - Agouza

Giza Governorate - Egypt

Has been accredited by EGAC in compliance with the requirements of

ISO 15189:2012

In Some Red Blood Cells Phenotyping Tests

The scope of accreditation is described in the attached schedule No. (052318B)

Scope Issue No. (01)

Issue No. (01): February 28, 2024 Valid to: December 31, 2025

Subject to continued compliance to the above standard and EGAC requirements

The laboratory is accredited to issue reports / certificates under EGAC accreditation according to the attached scope of accreditation

EGAC is an ILAC MRA Signatory in the Field of Calibration, Testing, Medical Labs, Proficiency Testing Providers and Inspection Bodies Accreditation

Eng. Hanie El Desouki

Executive Director

Egyptian Accreditation Council

Eng. Ahmed Samir Saleh

Chairman of EGAC

Minister of Trade and Industry

70661


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Idfu
Baris
Aswan
Lake Nasser
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Beersheba
Dead Sea
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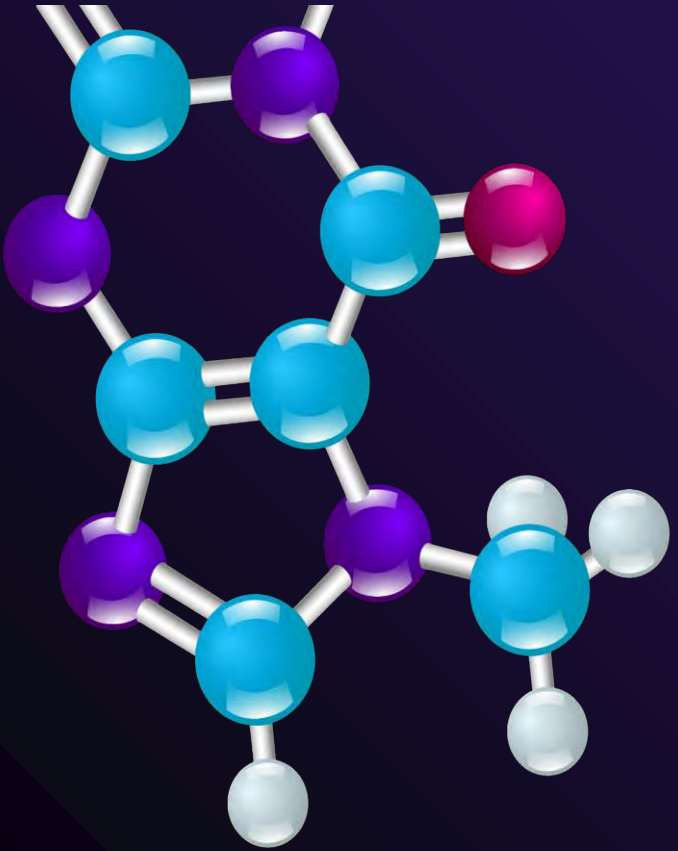
Gaza
IBYA
As Sallum

Governance of BTS in Egypt

- Egypt has a **National Blood Regulatory Council** that was enforced by the Egyptian law no. 8/2021 for Regulation of Blood and Blood Products which is headed by his excellency Minister of Health and population.
- The members of this council include representatives from all stakeholders of blood transfusion services as MoHP , University hospitals , NGOs, Health Insurance, Private, Military , Police blood banks in addition to GAHAR , Egyptian drug authority and Unified Procurement authority.
- It is responsible for setting National Blood system policies , Standards , regulations for licensing and Strategies to ensure homogenecity and governance for all stakeholders on the national level.

Screening For Transfusion Transmitted Infections (TTIS)

- All blood donations shall be screened for HBsAg, Anti-HCV, HIV Ag/Ab and Treponema Pallidum Ab before considered suitable for clinical use .
- Screening is done using EIA assays or chemiluminscence previously evaluated and validated by the Reference Laboratory before acceptance and use according to WHO protocol.
- All donations shall be tested by nucleic acid amplification technology (NAT).



Nucleic Acid Testing (NAT)

NAT testing is a method used to detect viral nucleic acids (DNA & RNA) directly in blood products. NAT is used as a screening tool for blood donations to detect viral infections in the early stages, during the window period when antibodies are not yet detectable.

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Nucleic Acid Testing (NAT)

- Highly sensitive and specific technique.
- Based on individual testing (ID) or mini pools of samples, using either transcription mediated amplification (TMA) or polymerase chain reaction (PCR) techniques.

Nucleic Acid Testing (NAT)

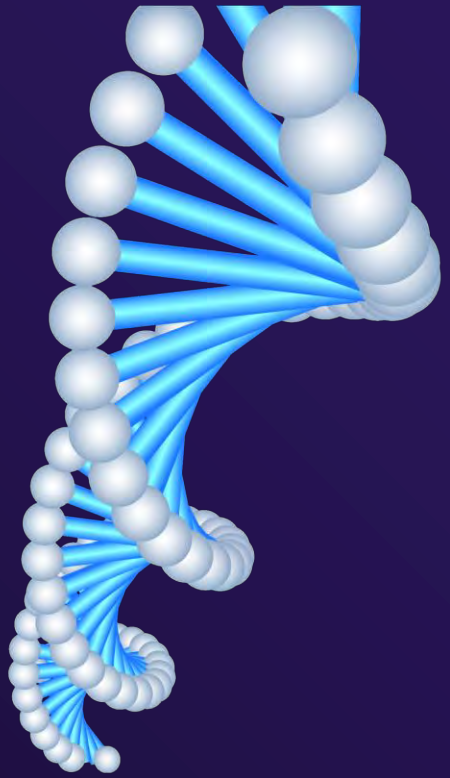
- NAT is complementary test to EIA or chemiluminscence screening.
- NAT testing will not replace the current serological tests in blood screening.

- National implementation of NAT as a milestone for enhancement of blood safety.

- Proposed plan to implement NAT in blood donor screening all over Egypt.

Introduction of NAT in NBTS

- NAT devices were introduced since 2009 to the NBTS for more than a decade now, and throughout all these years the efficiency was 100%, this means, neither faulty results ever generated nor were unsafe units ever released, we are talking about total of 500,000 tests/year



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Types of Equipment used in NBTS

Types of Equipment used in NBTS

Enhancing Blood Safety

- Nucleic Acid Testing (NAT) was introduced in 2009 in NBTC (headquarter) while now distributed to cover 94% RBTCs.

- Upgrading the screening strategy for TTIs from (ELISA) to fully automated modern technique Chemiluminescence in NBTC in 2016 to ensure more sensitive and specific test result & Now distributed in 89 % RBTCs.

Blood Testing Centralization Plan

- To ensure blood safety allover the country.
- To decrease the testing cost.
- To help monitoring & quality control of testing.

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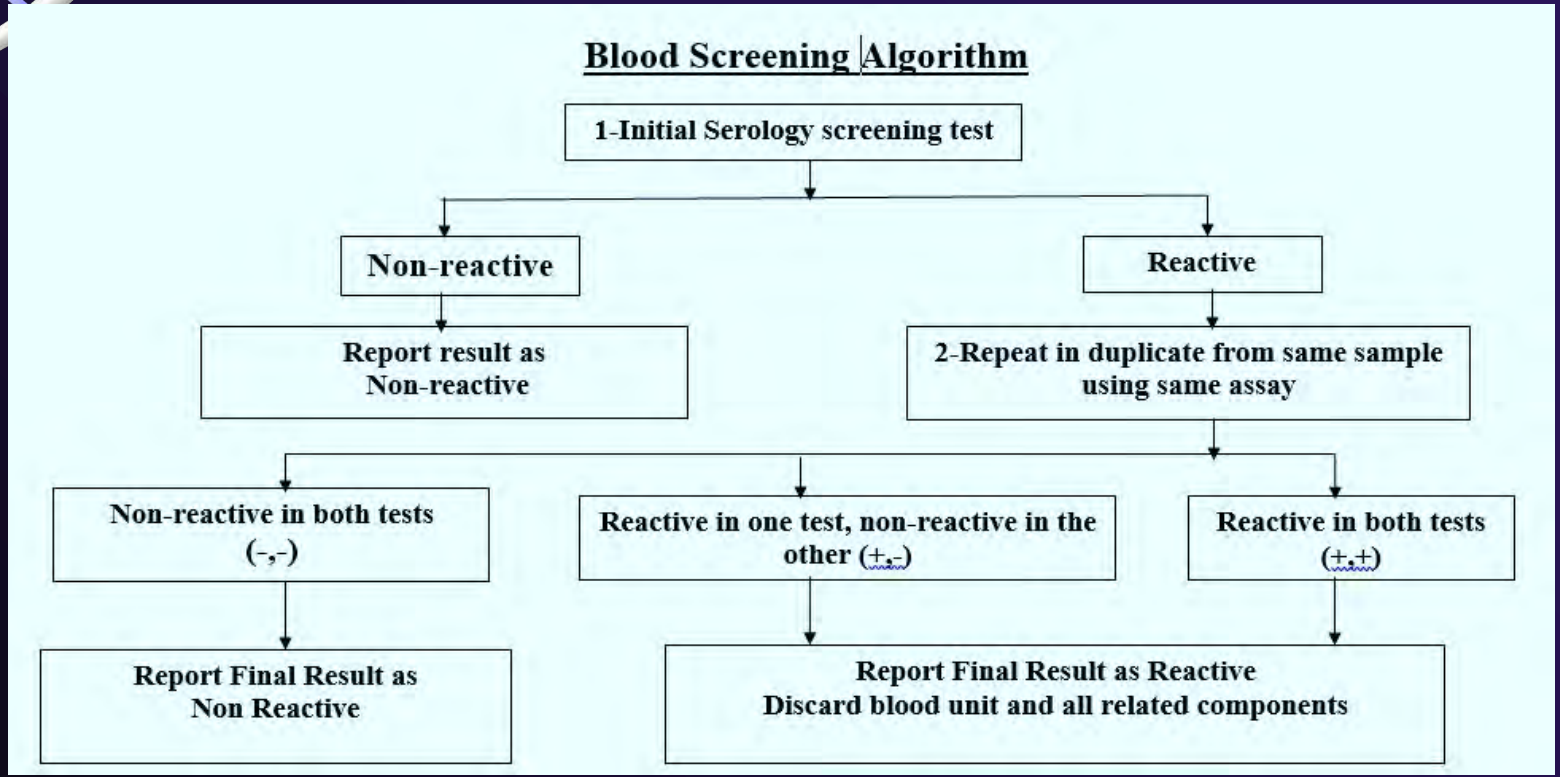
NBTS Blood Screening Algorithms



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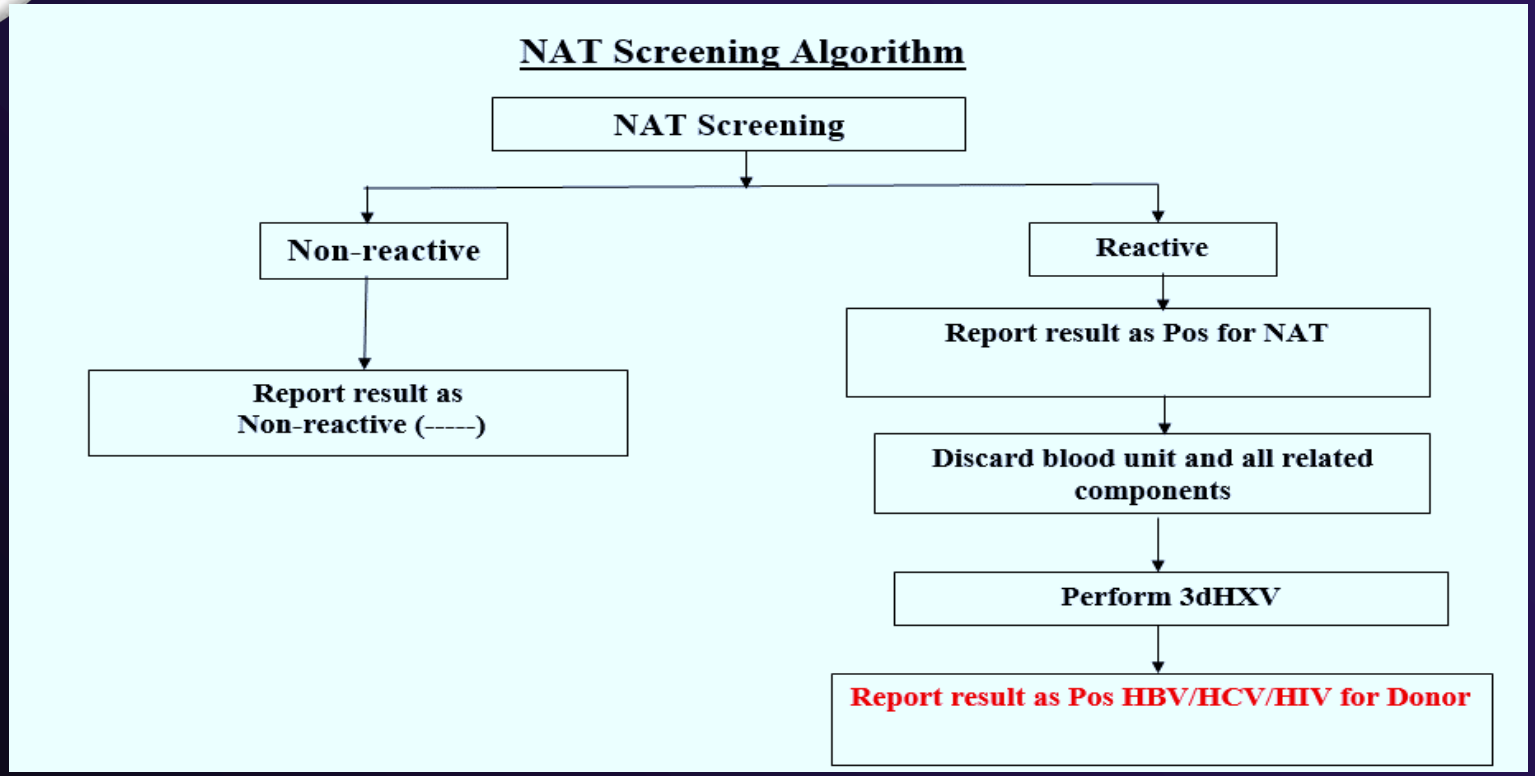
NAT Screening Algorithm



The Impact of NAT Testing in Blood Transfusion Centres

1. Reducing the risk of Transfusion-transmitted Infections.
2. Improving Blood Safety and Quality.
3. Enhancing Donor Screening and Selection.
4. Impact on Blood Supply and Availability: may lead to the exclusion of some potential blood donors who test positive for viral nucleic acids. This can result in a decrease in the number of available Blood Products, which can impact patient care.
5. Cost-Effectiveness: the cost of NAT testing is offset by the improved Safety and Quality of Blood Products, which leads to a reduction in the cost of treating Transfusion-related Complications.

Nucleic Acid Testing Comparative study between the seronegative blood donors within the Regional Blood Transfusion Centers in Egypt

- This retrospective study was conducted in 20 Regional Blood centers from 2015 to 2022, Seronegative samples collected to be further tested by NAT testing .

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Aim of The Study

01

Provide safe and effective blood and blood components

02

Updating the National Donor Deferral Registry NDDR with the data collected throughout the routine work of NBTS

03

Completion of the Hepatitis C virus elimination program all-over Egypt

04

Increasing and achieving optimal use of the Country resources regarding investments in projects, devices & infrastructure

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Conclusion

The Total Number of NAT Yield detected since (2015-2022) were (2025) samples out of total (3458000) tested blood units using the two NAT Testing Platforms, that could have been issued or transfused for patients, causing TTIs. as the units are being routinely processed, the number of possible components that could have been issued or transfused for patients is triple numbered (A unit is processed into: A Packed Red Blood Cells unit, a plasma unit, Cryoprecipitate/Platelet unit), which means that these units could have been transfused to about for almost (6000) persons/patients and that is considered of a very high Risk of transmitting viral infections to the community.

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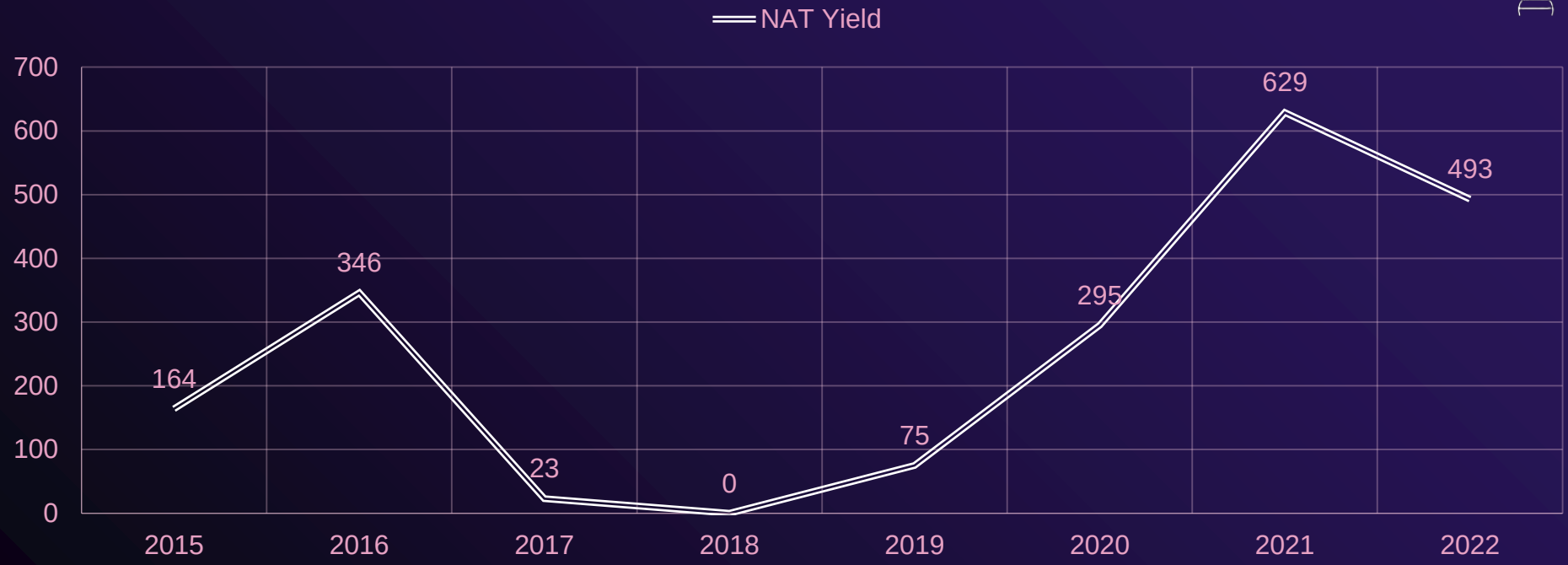
NAT YIELD



- **NAT Yield is average 0.1% of total tested NAT Samples**

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Recommendations

The NAT testing must be performed for all blood donations in Egypt to:

- **Ensure the safety of blood units collected, as a routine measure.**
- **The further studies that could be conducted in governorates with highly prevalent viral infection detected by NAT Testing could help in further investigation and for programs designed for eradicating such infection from our community.**
- **This would have been a disaster in the community due to the increased medical expenses, decreased productivity of those patients which in return will affect the national expenditure and decrease the national income and decrease the national Gross Domestic Product GDP.**

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Recommendations

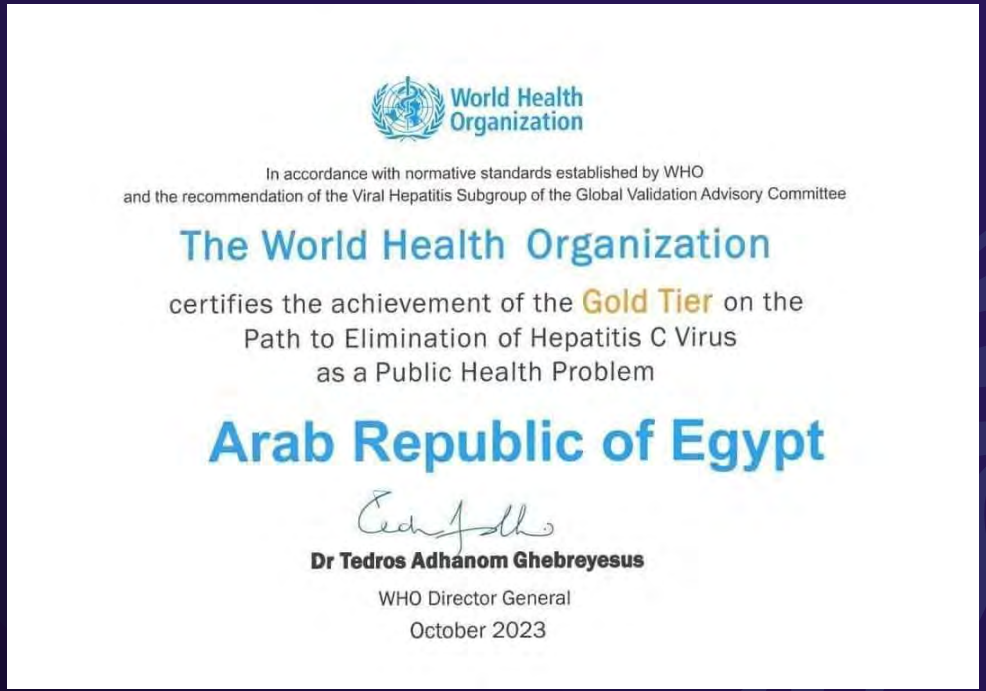
- The Epidemiological data extracted from these results annually helps in:
  1. Updating the national donor deferral list.
  2. National committees of HIV viruses' eradication in Egypt.
  3. National committees of HCV viruses' eradication in Egypt.
  4. National Initiative 100 M Health for HCV eradication.

Hepatitis C Elimination

Achieving the GOLD TIER on the path of Hepatitis C elimination

The Arab Republic of Egypt has become the first country to achieve the "Gold Tier" status on the path to elimination of Hepatitis C as per WHO criteria. This means that Egypt has fulfilled WHO's programmatic coverage targets that will set the country up to achieve the reduced incidence and mortality targets of full elimination before 2030.

WHO commends Egypt for its progress on the path to eliminate Hepatitis C



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NBTS Role in Hepatitis C Elimination

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National Blood Transfusion Services prepared the **Blood Safety** file in the Egyptian dossier presented to WHO .

To elaborate the blood system in Egypt in terms of governance and the efforts exerted in the last two decades in upgrading of screening techniques to the latest technologies in Transfusion medicine and the implementation of NAT.

Thank you

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