Transmissible diseases through ocular tissues transplantation

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Fondazione Banca degli Occhi del Veneto

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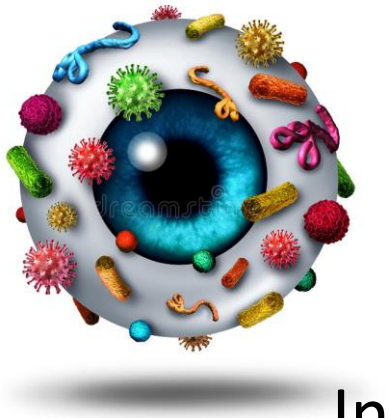
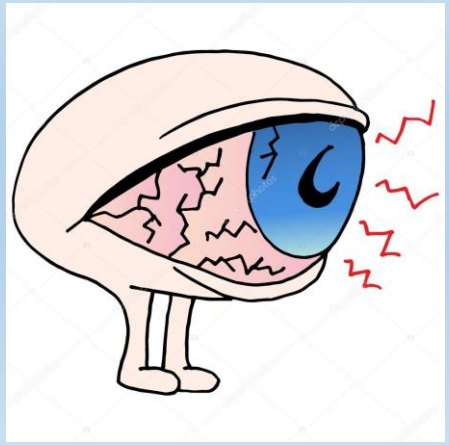


In some respects, the cornea has a low risk of diseases transmission, due to its poor vascularization, but for others the dense innervation (is the most densely innervated tissue of the body) makes the cornea a vehicle of diseases affecting the nervous system.



Regulatory framework for tissue and donor selection

- DIRETTIVA 2004/23/CE DEL PARLAMENTO EUROPEO E DEL CONSIGLIO del 31 marzo 2004 sulla definizione di norme di qualità e di sicurezza per la donazione, l'approvvigionamento, il controllo, la lavorazione, la conservazione, lo stoccaggio e la distribuzione di tessuti e cellule umani.
- DIRETTIVA 2006/17/CE DELLA COMMISSIONE dell'8 febbraio 2006 che attua la direttiva 2004/23/CE del Parlamento europeo e del Consiglio per quanto riguarda determinate prescrizioni tecniche per la donazione, l'approvvigionamento e il controllo di tessuti e cellule umani.
- DIRETTIVA 2000/86/CE DELLA COMMISSIONE del 24 ottobre 2006 che attua la direttiva 2004/23/CE del Parlamento europeo e del Consiglio per quanto riguarda le prescrizioni in tema di rintracciabilità, la notifica di reazioni avverse ed eventi avversi gravi e determinate prescrizioni tecniche per la codifica, la lavorazione, lo stoccaggio e la distribuzione di tessuti e cellule umani.
- DIRETTIVA 2012/39/UE DELLA COMMISSIONE del 26 novembre 2012 che modifica la direttiva 2006/17/CE per quanto riguarda determinate prescrizioni tecniche relative agli esami effettuati su tessuti e cellule umani.
- D.Lgs. 6/11/07 n. 191 Attuazione della direttiva 2004/23/CE sulla definizione delle norme di qualità e di sicurezza per la donazione, l'approvvigionamento, il controllo, la lavorazione, la conservazione, lo stoccaggio e la distribuzione di tessuti e cellule umani.
- D.Lgs. 25/01/10 n. 16 Attuazione delle direttive 2006/17/CE e 2006/86/CE, che attuano la direttiva 2004/23/CE per quanto riguarda le prescrizioni tecniche per la donazione, l'approvvigionamento e il controllo di tessuti e cellule umani, nonché per quanto riguarda le prescrizioni in tema di rintracciabilità, la notifica di reazioni ed eventi avversi gravi e determinate prescrizioni tecniche per la codifica, la lavorazione, la conservazione, lo stoccaggio e la distribuzione di tessuti e cellule umani.
- D.Lgs. 30/05/12 n. 85 Modifiche ed integrazioni al decreto legislativo 25 gennaio 2010, n. 16, recante attuazione delle direttive 2006/17/CE e 2006/86/CE, che attuano la direttiva 2004/23/CE per quanto riguarda le prescrizioni tecniche per la donazione, l'approvvigionamento e il controllo di tessuti e cellule umani, nonché per quanto riguarda le prescrizioni in tema di rintracciabilità, la notifica di reazioni ed eventi avversi gravi e determinate prescrizioni tecniche per la codifica, la lavorazione, la conservazione, lo stoccaggio e la distribuzione di tessuti e cellule umani.
- Linee guida per il prelievo, la processazione e la distribuzione di tessuti a scopo di trapianto approvate dal Centro Nazionale Trapianti, settembre 2016

HIV-1 and HIV-2

FEATURES

- RNA retrovirus.
- HIV-1: most common etiological agent of AIDS.
- HIV-2: it is considered less infectious and less virulent than HIV-1. HIV-2 causes immunodeficiency and neurological syndrome.

HIV-1 and HIV-2

TRANSMISSION FROM DONOR TO RECIPIENT

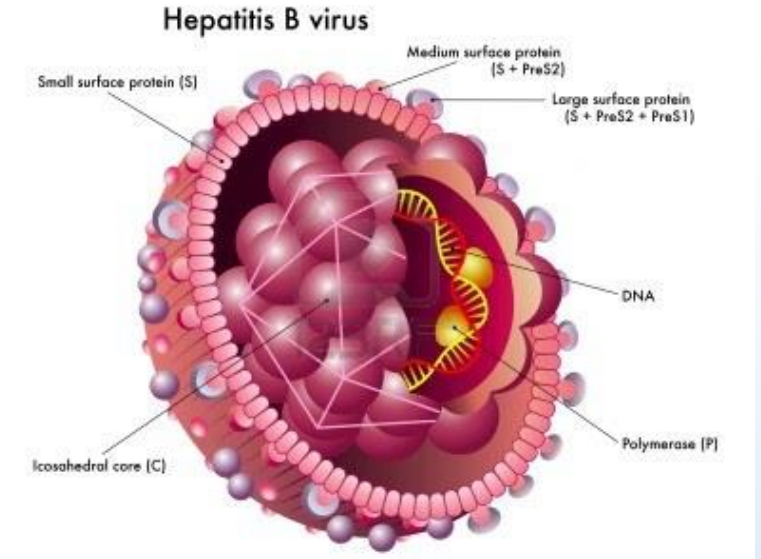
No transmission documented, despite 9 recipients received corneas from HIV reactive donors before the mandatory screening was introduced.

The amount of HIV 1 virus in the cornea and tears of seropositive patients is low and this makes transmission of the virus difficult through corneal transplantation.

PREVENTION

- HIV 1-2 antibodies and NAT test with validated kit.
- Physical inspection and review of medical and behavioral history of donor.

Hepatitis B virus



FEATURES

DNA Hepadnavirus.

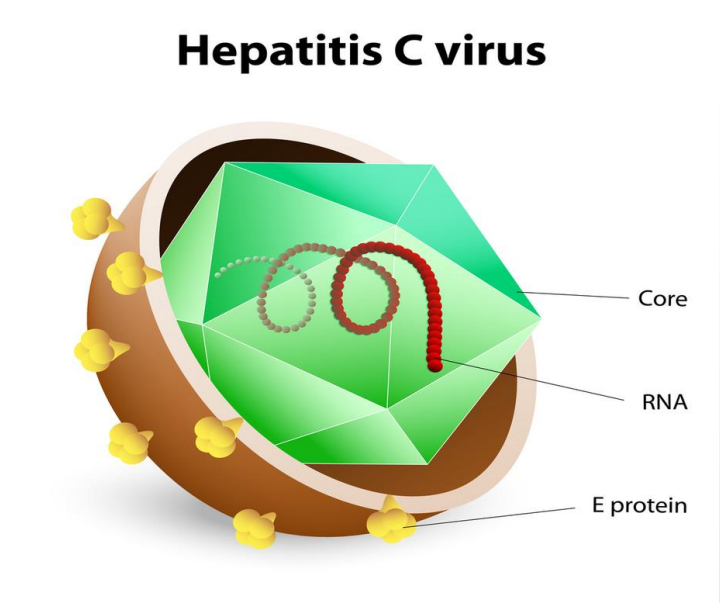
TRANSMISSION FROM DONOR TO RECIPIENT

Two cases of transmission from two donors, before the introduction of mandatory screening (in 1984 and 1985).

PREVENTION

- HBsAg, HBc Ab and NAT test with validated kit.
- Physical inspection and review of medical and behavioral history of donor.

Hepatitis C virus



FEATURES

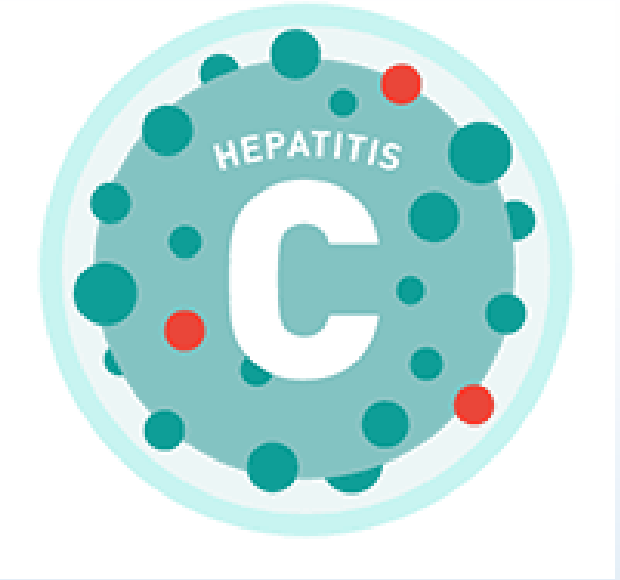
RNA flavivirus.

TRANSMISSION FROM DONOR TO RECIPIENT

No transmission documented, despite 6 recipients received corneas from HCV reactive donors before the mandatory screening was introduced.

The amount of HCV virus in the cornea of seropositive patients is absent/low and this makes transmission of the virus improbable through corneal transplantation.

Hepatitis C virus



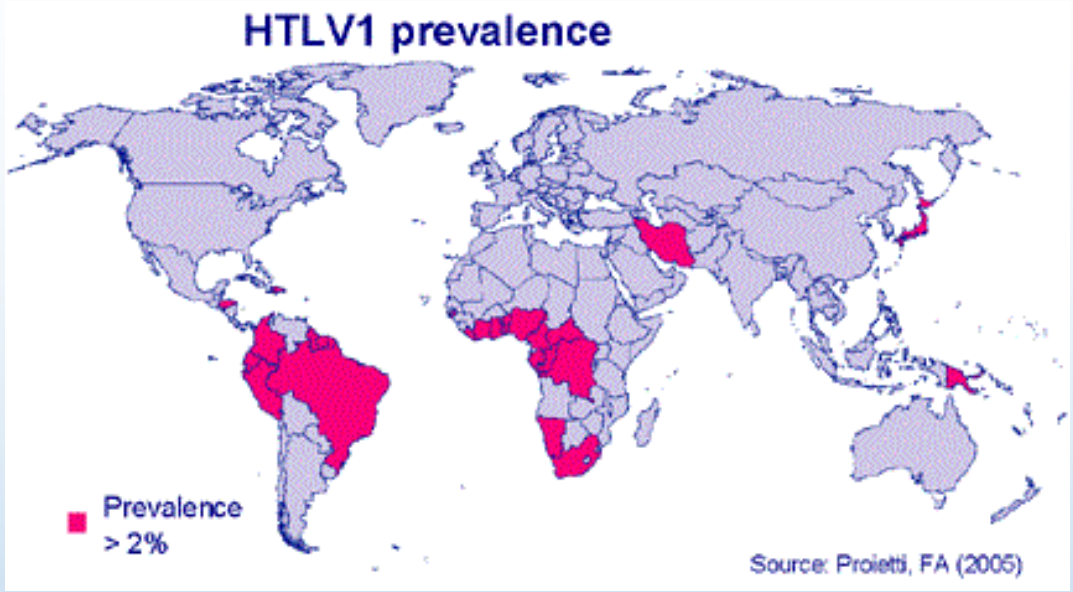
PREVENTION

- HCV antibodies and NAT test with validated kit.
- Physical inspection and review of medical and behavioral history of donor.

HTLV-I and HTLV-II (Human T-Cell Lymphotropic Virus)

FEATURES

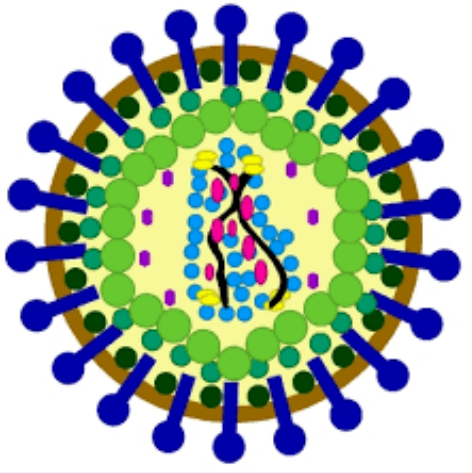
- RNA retrovirus.
- HTLV-I: adult T-cell lymphoma.
- HTLV-II: hairy cell leukemia.



TRANSMISSION FROM DONOR TO RECIPIENT

- No transmission documented.
- Transmission of the virus by corneal transplantation is unlikely.

HTLV-I and HTLV-II



PREVENTION

HTLV-I/II antibodies in donors who live in high prevalence areas or who are originating or whose sexual partners come from such areas, or where the donor's parents are from these areas.

Treponema pallidum

FEATURES

Gram negative spirochete.

TRANSMISSION FROM DONOR TO RECIPIENT

- No transmission documented.
- The very low vitality of the spirochete in the preservation medium makes unlikely the transmission.
- Generally considered marker of behavioral risk.

Treponema pallidum

PREVENTION

CLIA/EIA Ab; TPHA/TPPA; VDRL/RPR test.

- CLIA/EIA or TPHA/TPPA non reactive = suitable donor
- CLIA/EIA or TPHA/TPPA reactive = perform VDRL/RPR
  - VDRL/RPR non reactive = previous infection = suitable donor
  - VDRL/RPR reactive = recent infection = unsuitable donor

Malignancy

TRANSMISSION

Documented transmission of retinoblastoma (1939) and adenocarcinoma (1994) from donor to recipient.

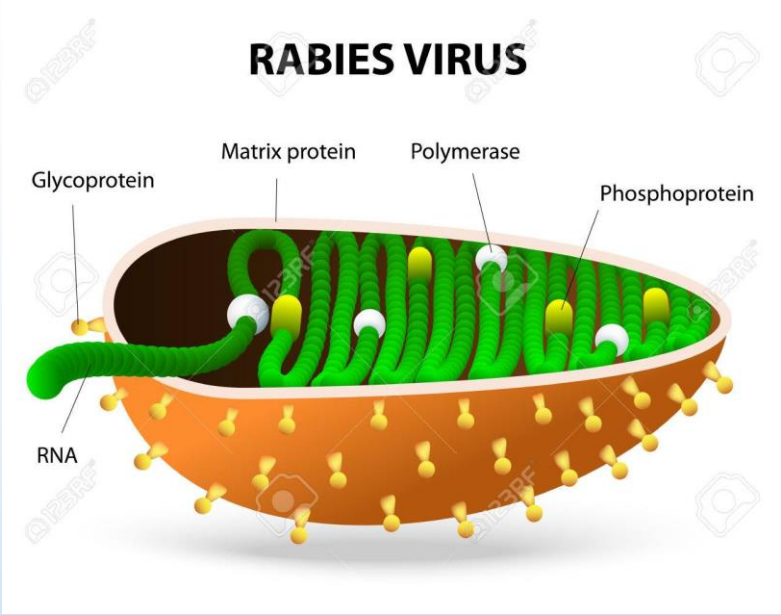
Based on the scientific literature, the use of corneas from neoplastic donors doesn't change the life expectancy of recipients.

PREVENTION

Exclusion from donation due to retinoblastoma, hematological neoplasm (such as leukemia, lymphoma, myeloma) and malignant tumors of the anterior segment of the eye.

In the case of donors with malignant diseases and a potential risk of metastasis formation in the anterior ocular segment, a thorough slit-lamp and/or light microscope examination of the globe or the corneo-scleral disc focused on possible metastasis must be undertaken in the eye bank.

Rabies virus



FEATURES

RNA retrovirus.

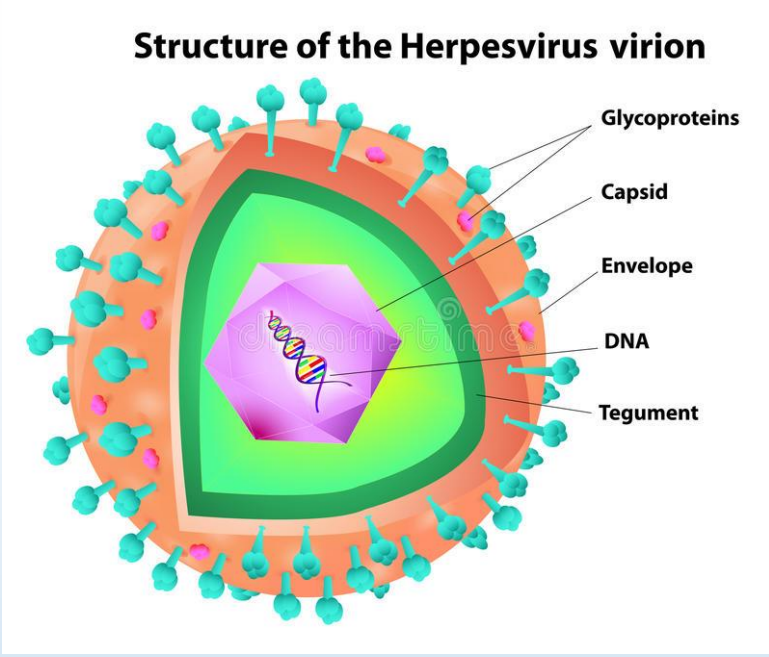
TRANSMISSION FROM DONOR TO RECIPIENT

Documented transmission in 8 patients before 1980.

PREVENTION

Exclusion from donation due to neurological disease of unknown etiology, active encephalitis, progressive encephalopathy, unknown cause of death.

Herpes virus



FEATURES

- DNA Herpesviridae.
- HSV-1: labial, ocular infection.
- HSV-2: genital infection.

TRANSMISSION FROM DONOR TO RECIPIENT

Clinical reports documented the transmission of HSV-1 virus by corneal transplantation.

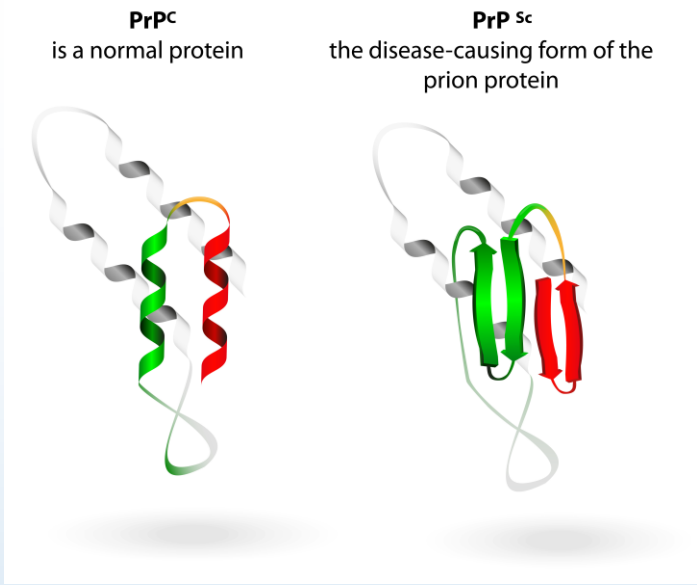
The most frequent consequence is primary graft failure, but cases of herpetic keratitis are also reported.

Herpes virus

PREVENTION

- Exclusion of donors with ocular infections.
- Discharging corneas (also the fellow) showing endothelium necrosis after trypan blue staining and light microscope evaluation.

Creutzfeldt–Jakob disease



FEATURES

- Prion disease.
- Incidence: 1-1,5 case/year per 1 million population.
- Sporadic (sMCJ); familiar (fMCJ); iatrogenic (iMCJ); new variant (vMCJ) identified for the first time in 1996.

TRANSMISSION FROM DONOR TO RECIPIENT

Four documented cases of transmission: 1 ascertained, 1 probable and 2 possible.

Creutzfeldt–Jakob disease

PREVENTION

- People diagnosed with CJD, or its variant, or with family history of non-iatrogenic CJD.
- History of rapidly progressing dementia or neurological diseases, degenerative diseases, including pathologies of unknown origin.
- Receiving hormones deriving from the human hypophysis, receiving grafts of cornea, sclera and dura mater as well as people who have undergone not well documented neurosurgery (in which the dura mater may have been used).
- Donors who have undergone surgery or blood/blood products transfusion in the UK from 1980 to 1996.

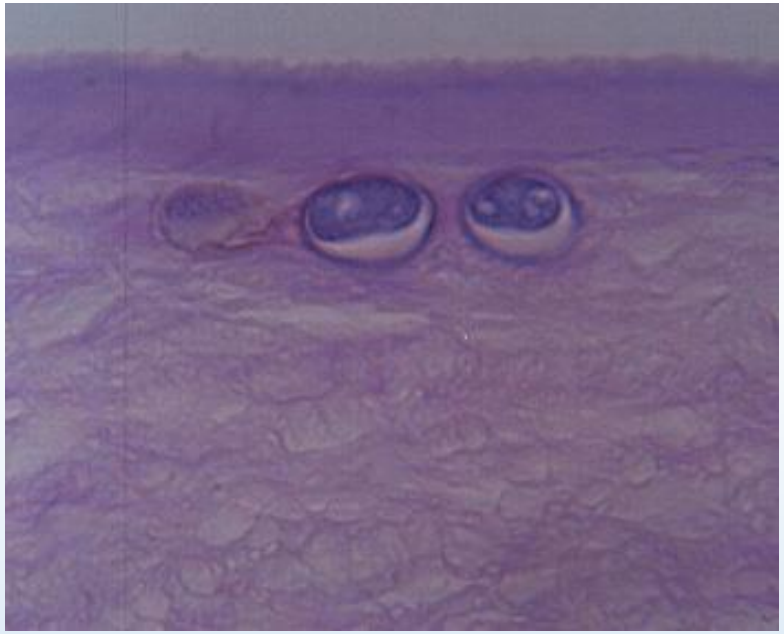
Keratitis - Endophthalmitis

- The incidence of post-op endophthalmitis and keratitis is infrequent (0.04- 0.3%).
- From 1972 to 2002 there was a 50% reduction in post-transplant endophthalmitis.
- There is no difference between post-op infections between EK flaps prepared by the bank and those prepared in the operating room by the surgeon.

PREVENTION

- Exclusion from donation due to ocular infections.
- Microbiological testing of media samples is mandatory if corneas are stored at 30/37°C (organ culture technique).

Acanthamoeba

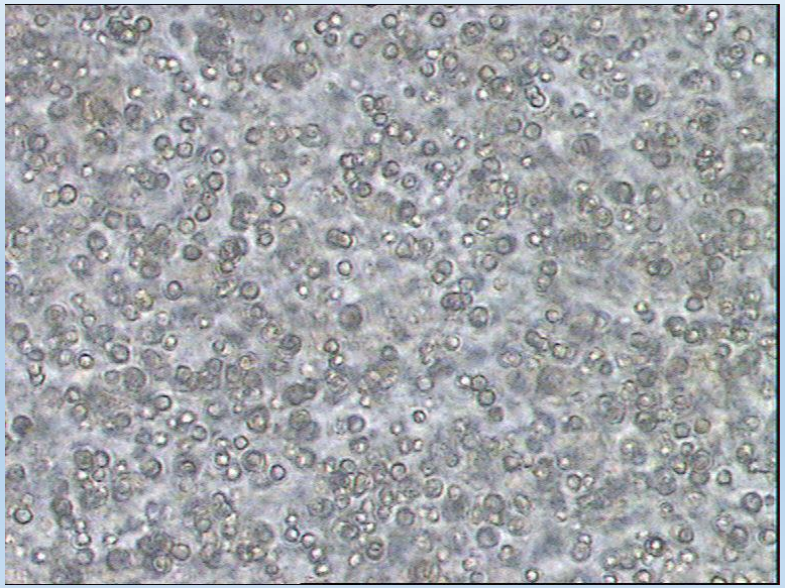


FEATURES

- Ubiquitous amoeba.
- 1.5 cases/million/year in contact lens wearers (USA).

TRANSMISSION FROM DONOR TO RECIPIENT

Two cases of transmission with corneas from asymptomatic donor.



PREVENTION

- Review of medical history.
- Light microscopy evaluation.

Scientific references

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SIBO

Società Italiana Banche degli Occhi

Thanks for your attention!