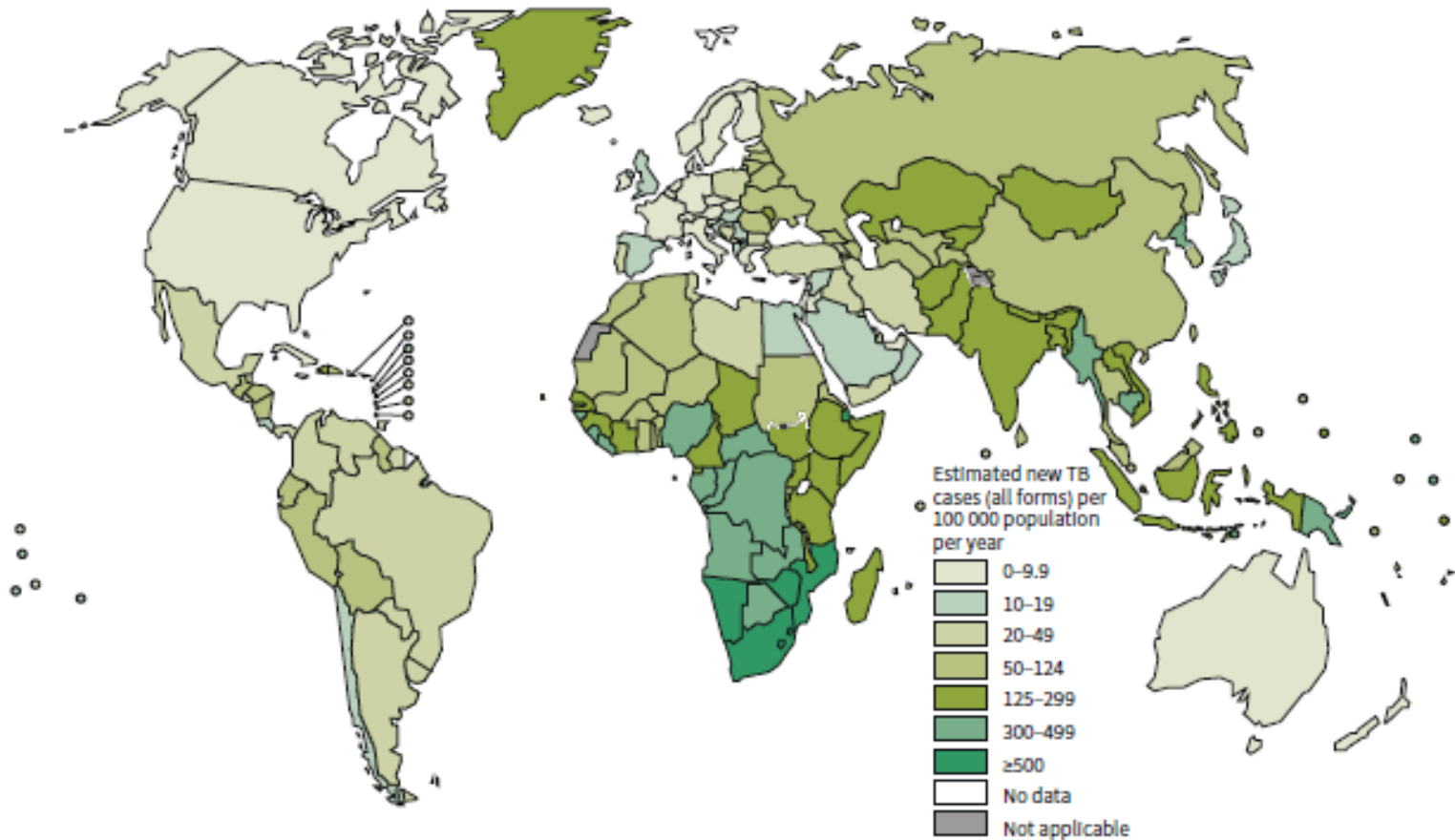


FIGURE 2.5

Estimated TB incidence rates, 2013



**General introduction of the QuantiFERON Gold In-Tube**

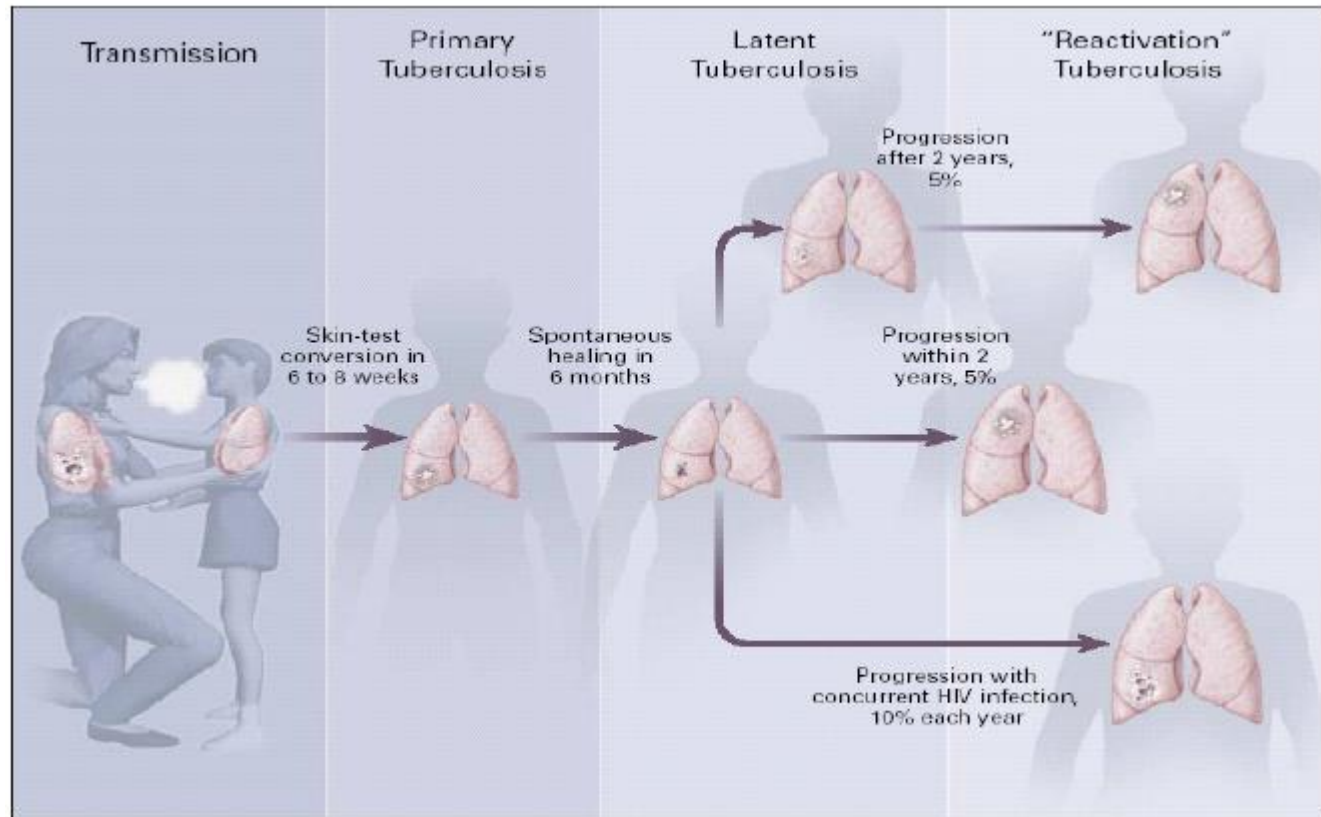
免疫組:洪嘉澤

UCL



# Introduction of TB

- **Tuberculosis (TB)** remains one of the world's deadliest communicable diseases. In 2013, an estimated 9.0 million people developed TB and 1.5 million died from the disease.
- TB is slowly declining each year and it is estimated that 37 million lives were saved between 2000 and 2013.
- Death toll from the disease is still unacceptably high and efforts to combat it must be accelerated if 2015 global targets, set within the context of the Millennium Development Goals (MDGs), are to be met.



**Figure 3.** Transmission of Tuberculosis and Progression from Latent Infection to Reactivated Disease.

# TB diagnostics

- Complete medical evaluation for TB must include a **medical history**, a **physical examination**, a **chest X-ray** and **microbiological examination** (of sputum or some other appropriate sample).
- It may also include a **tuberculin skin test(TST)**, other scans and surgical biopsy.
- The most common method for diagnosing TB worldwide is **sputum smear microscopy** (developed more than 100 years ago).

# Introduction of TST

- TST known as the **Mantoux screening test, tuberculin sensitivity test, Pirquet test, or PPD test** for purified protein derivative.
- The person's medical risk factors determine at which increment (5 mm, 10 mm, or 15 mm) of induration the result is considered positive.<sup>.CDC</sup>
- Alternative criteria include increases of 6, 12, 15 or 18 mm.<sup>.ROC</sup>

# IFN- $\gamma$ release assay(IGRA)

- QuantiFERON-TB Gold (Liquid antigen version)
  - Liquid antigen version
  - Specific antigen : ESAT-6, CFP-10
  - FDA, Japanese MHLW, CE Marking, CDC and JST guidelines
- **QuantiFERON-TB Gold In Tube**
  - In Tube version
  - Specific antigen : ESAT-6, CFP-10, TB7.7
  - Replaces the liquid antigen version. FDA and Japan approved, Canadian approved....., CE Marked, US and European guidelines
- **T Spot TB**
  - Liquid antigen
  - Specific antigen : ESAT-6, CFP-10
  - Canadian approved, CE Marked, European guidelines, FDA approved.

# QuantiFERON® TB Gold In-Tube

## Blood Collection Tubes

**Nil control** —negative control

**TB antigen** —ESAT-6, CFP-10, TB7.7

ex. *M. kansasii*, *M. szulgai* and *M. marinum*

**Mitogen** —especially warranted to the individual's immune status.

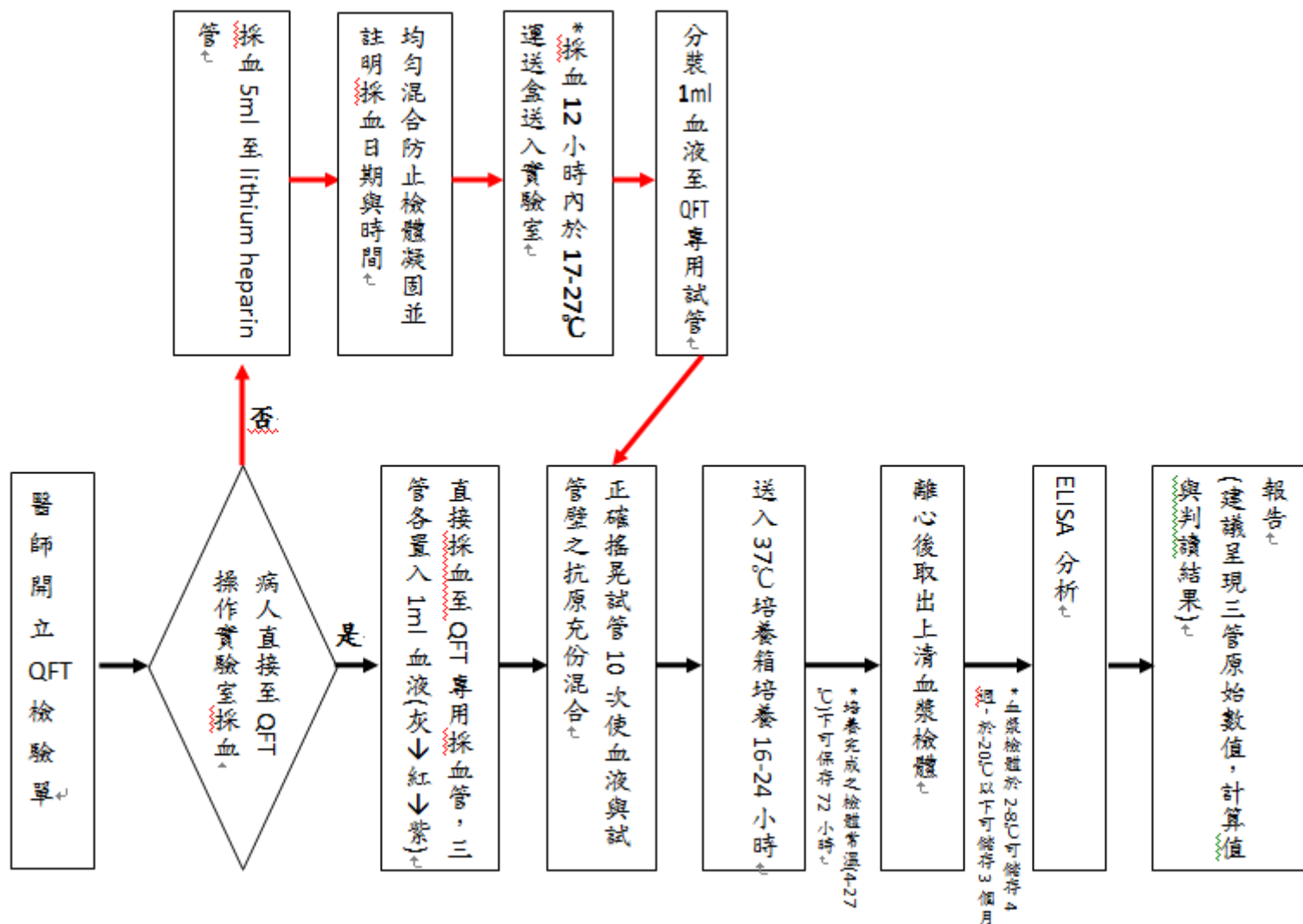
## Reagent

**ELISA Kit** —ELISA analysis



# 中華民國風濕病醫學會

## QFT採檢送檢建議 2013.5.4





# QTF Analysis

QFT results are interpreted using the following criteria:

Table 2. When Nil, TB Antigen, and Mitogen tubes are used

Nil (IU/ml)	TB Antigen minus Nil (IU/ml)	Mitogen minus Nil (IU/ml)*	QFT result	Report/Interpretation
≤8.0	< 0.35	≥ 0.5	Negative	<i>M. tuberculosis</i> infection NOT likely
	≥ 0.35 and < 25% of Nil value	≥ 0.5	Negative	<i>M. tuberculosis</i> infection NOT likely
	≥ 0.35 and ≥ 25% of Nil value	Any	Positive <sup>†</sup>	<i>M. tuberculosis</i> infection likely
	< 0.35	< 0.5	Indeterminate <sup>‡</sup>	Results are indeterminate for TB-Antigen responsiveness
	≥ 0.35 and < 25% of Nil value	< 0.5	Indeterminate <sup>‡</sup>	Results are indeterminate for TB-Antigen responsiveness
> 8.0 <sup>§</sup>	Any	Any	Indeterminate <sup>‡</sup>	Results are indeterminate for TB-Antigen responsiveness

# Factors Associated with Indeterminate

- **Age**
  - The median age of the indeterminate group was 70.5 years.
- **Lymphocytopenia**
- **CRP elevation**
- **Hypoproteinemia**

# CDC recommendations

## Risk factors for *TB* infection

- Close contacts
- Foreign-born persons from areas or frequently visit areas that have a high incidence of active TB (e.g., Africa, Asia, Eastern Europe, Latin America, and Russia)
- Health-care workers
- Medical underserved, low-income populations
- Infants, children, and adolescents exposed to adults who are at increased risk for LTBI or active TB.

# CDC recommendations

## Risk factors for progression of infection to active tuberculosis

- HIV infection
- Infants and children aged <5 years
- Persons who are receiving immunosuppressive therapy
- Persons who were recently infected with TB (within the past 2 years)
- Persons with a history of untreated or inadequately treated active TB
- Persons with silicosis, diabetes mellitus, chronic renal failure, leukemia, lymphoma, or cancer of the head, neck, or lung
- Persons who weigh <90% of their ideal body weight
- Cigarette smokers and persons who abuse drugs or alcohol
- Medical underserved or low-income populations