



Principles and rules of **uncertainty** and its place in the laboratory for test results

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کارگاه آموزشی سیستم مدیریت کیفیت در
آزمایشگاه های تشخیص پزشکی
بر مبنای ISO 15189:2022

سندج

۳۱ مرداد و ۱ شهریور ۱۴۰۳



ISO 15189: 2022 (7-3-4)

- The MU of measured quantity values shall be evaluated and maintained for its intended use, where relevant.
- The MU shall be compared against performance specifications and documented.
- MU evaluations shall be regularly reviewed.
- MU information shall be made available to laboratory users on request.
- If the qualitative result of an examination relies on a test which produces quantitative output data and is specified as positive or negative, based on a threshold, MU in the output quantity shall be estimated using representative positive and negative samples.

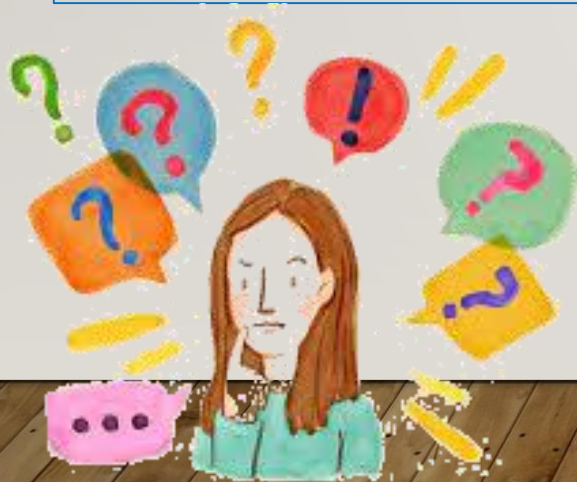
Concept Of Uncertainty



What's The Problem?

“We wish to add that **“few are truly aware of how to calculate MU in medical laboratories”**”.

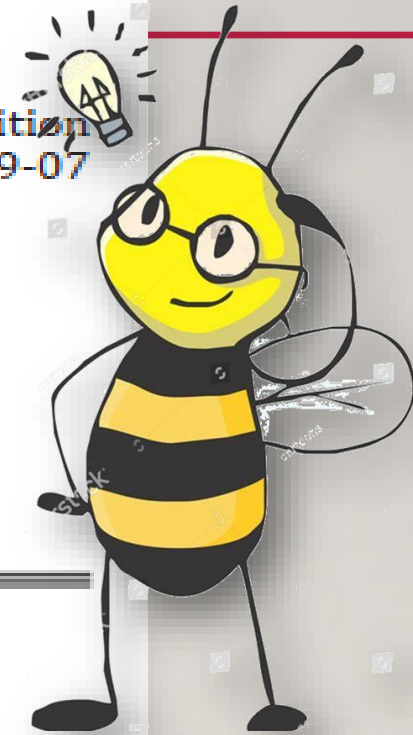
Mario Plebani, Andrea Padoan and Laura Sciacovelli Measurement uncertainty: light in the shadows <https://doi.org/10.1515/cclm-2020-0134>



**TECHNICAL
SPECIFICATION**

**ISO/TS
20914**

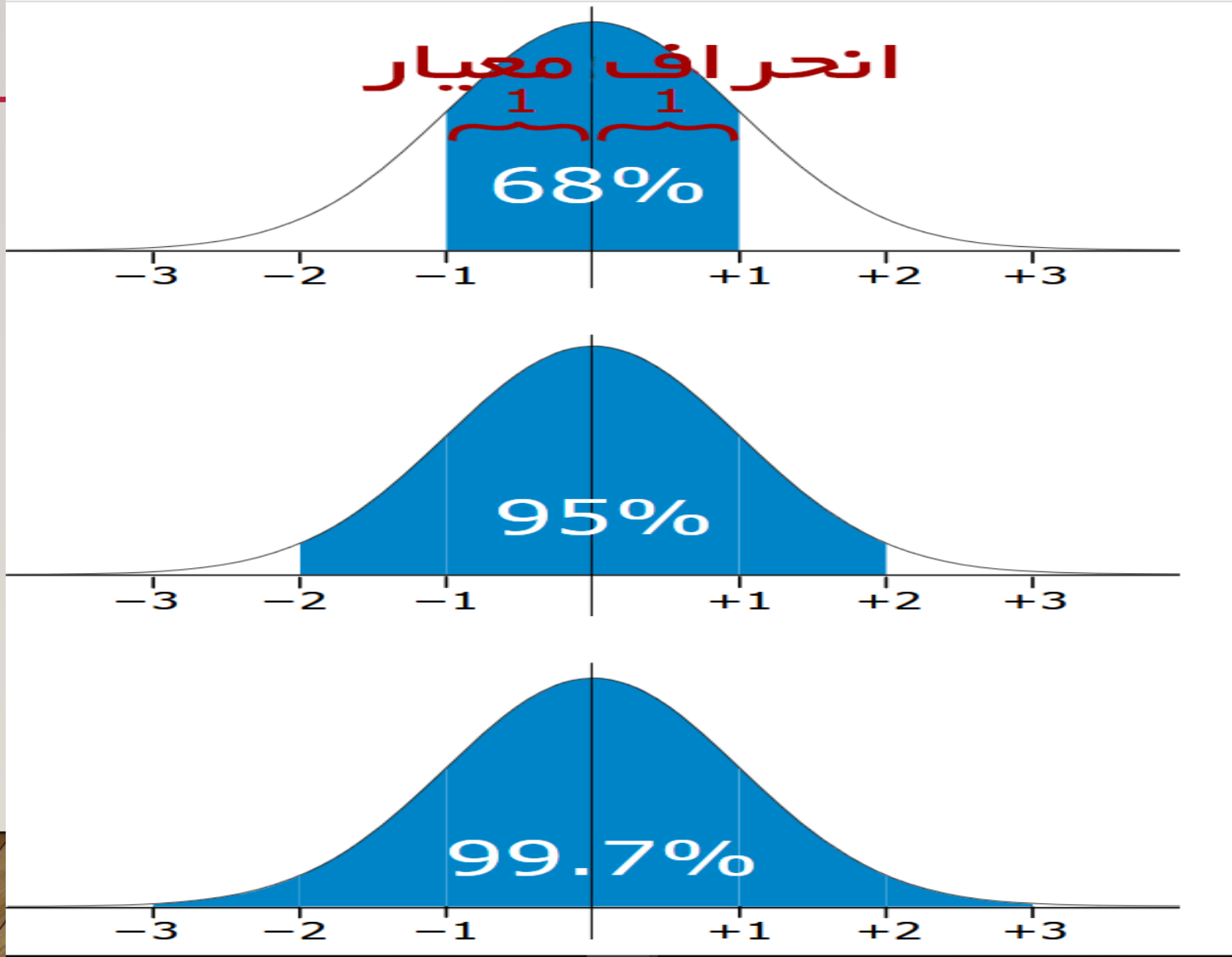
First edition
2019-07

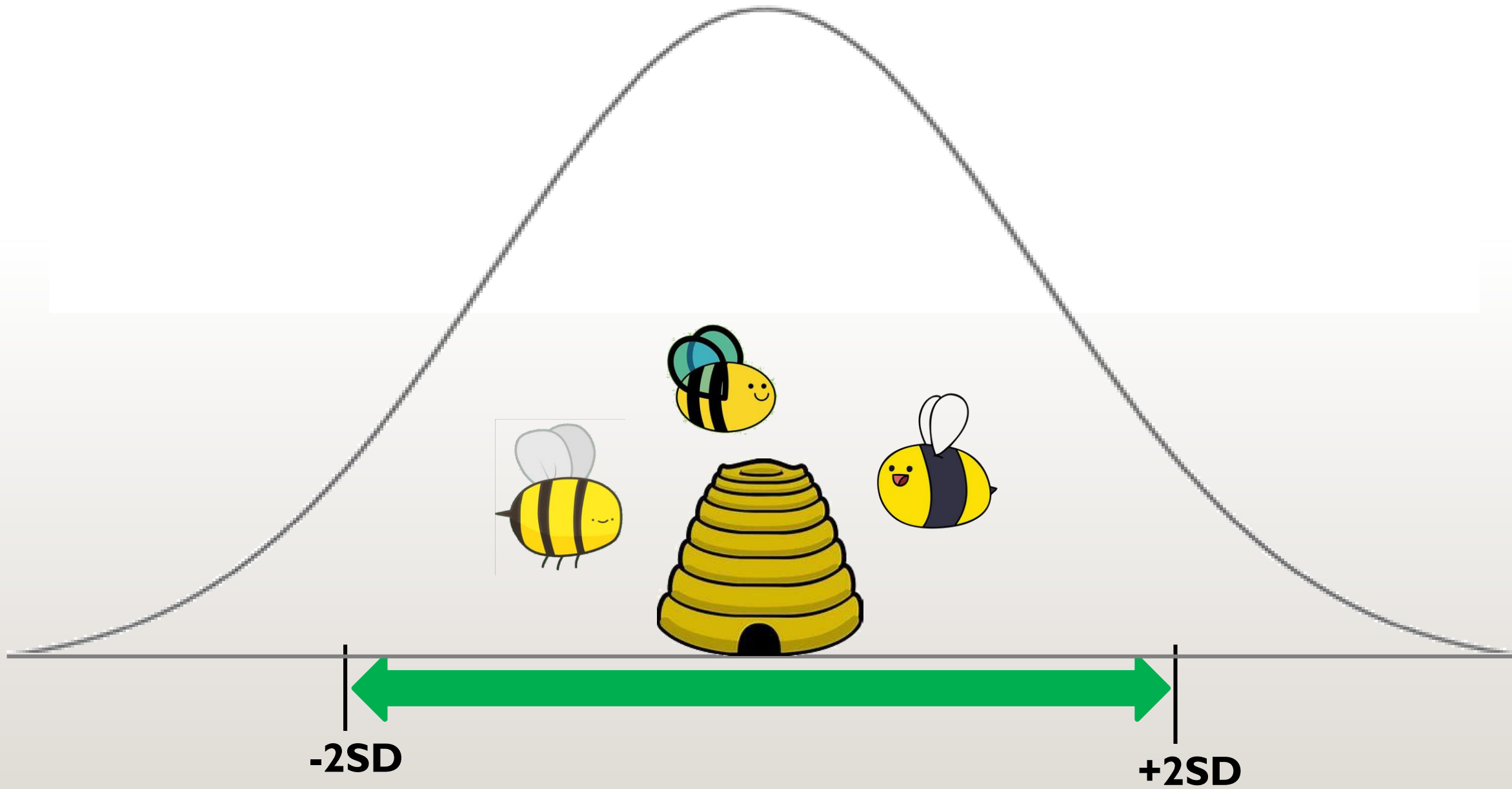


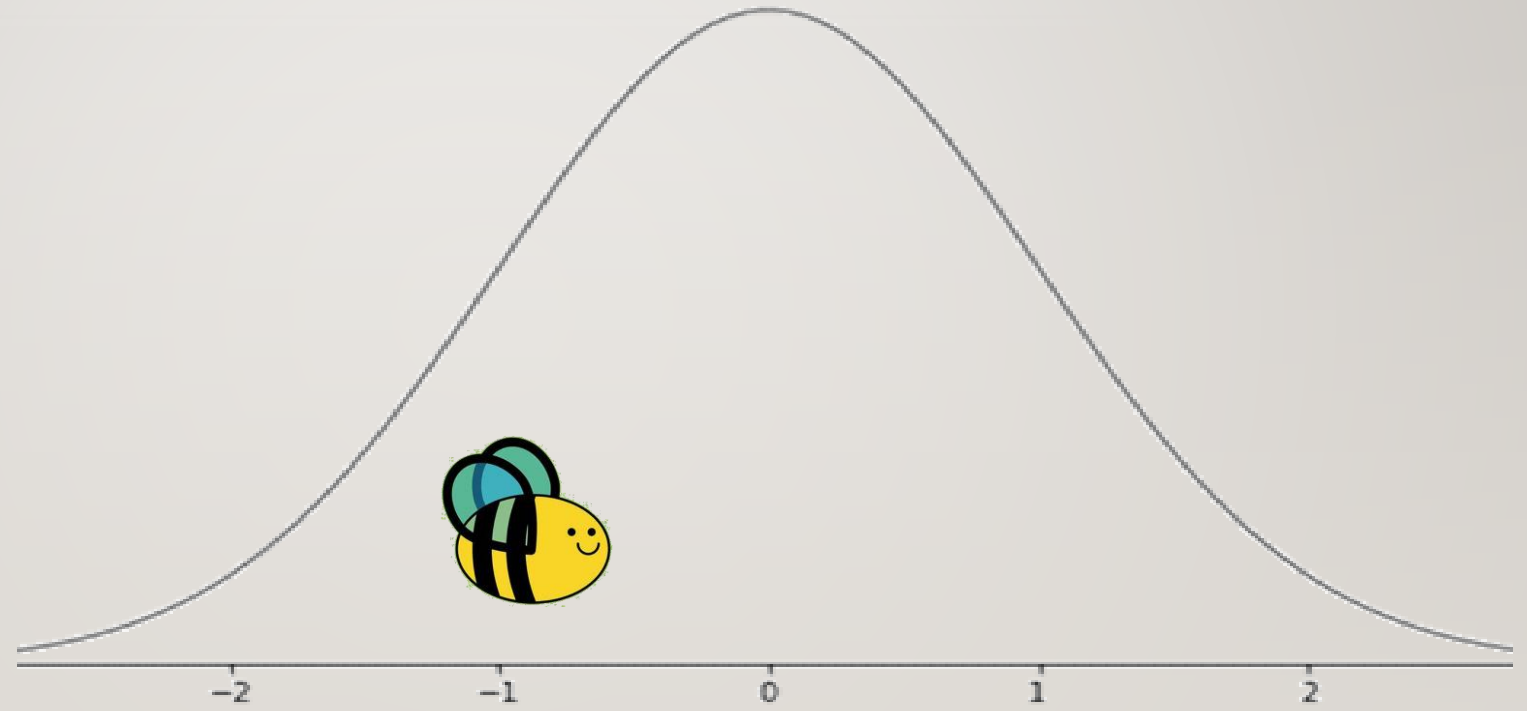
**Medical laboratories — Practical
guidance for the estimation of
measurement uncertainty**

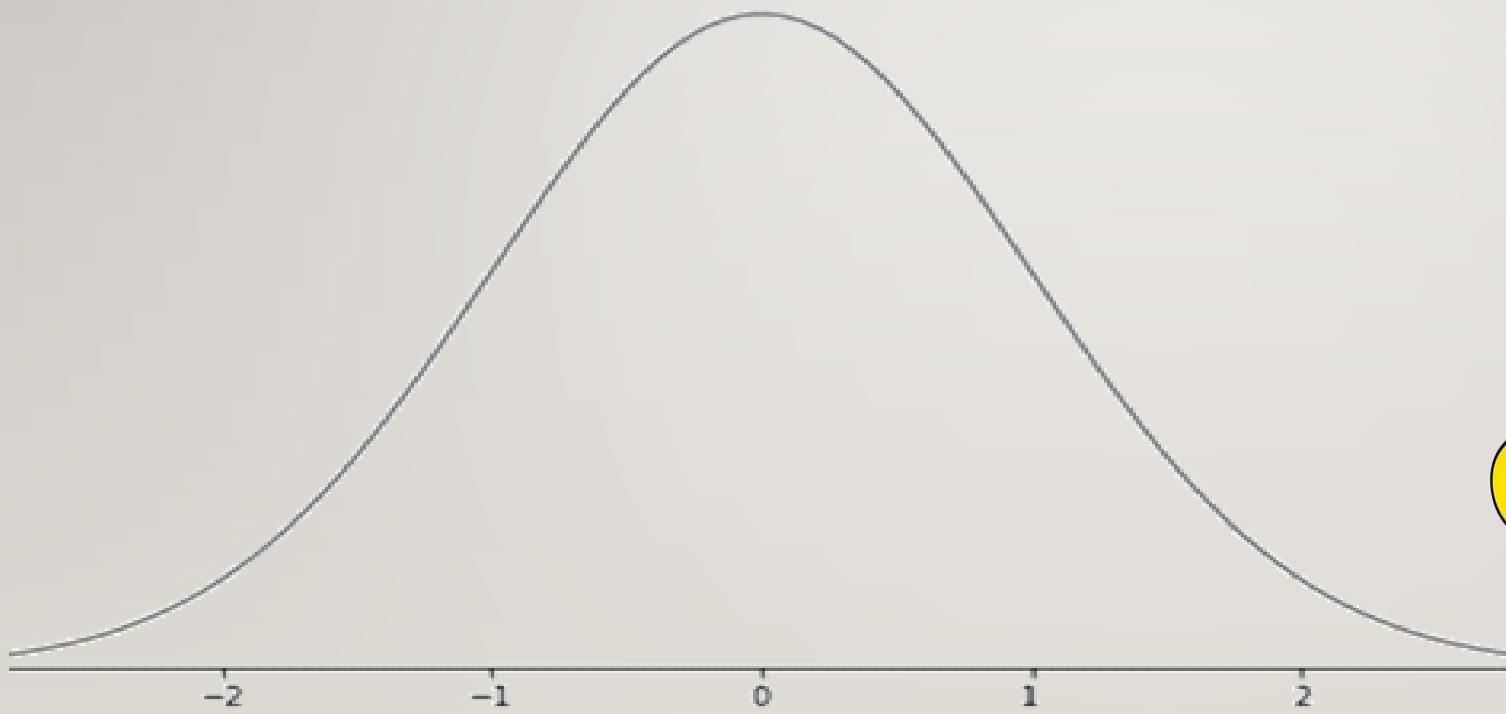
*Laboratoires médicaux — Lignes directrices pratiques pour
l'estimation de l'incertitude de mesure*

Normal (Gaussian) Distribution

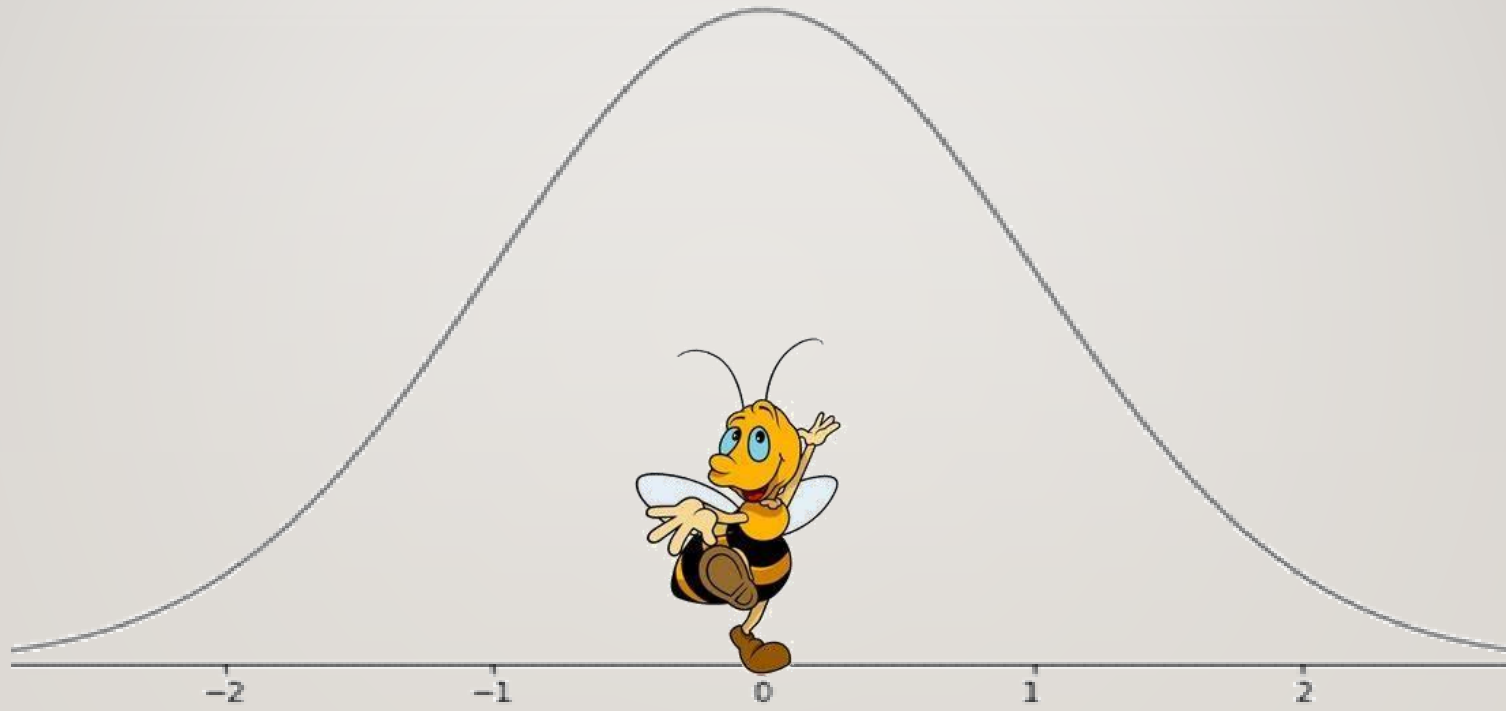


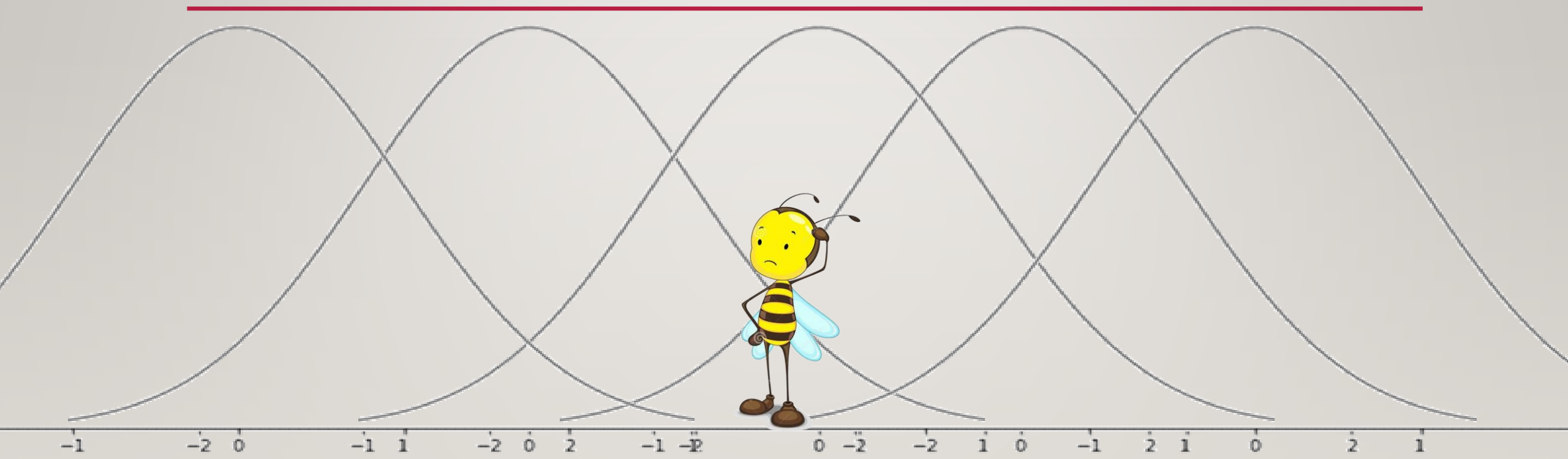


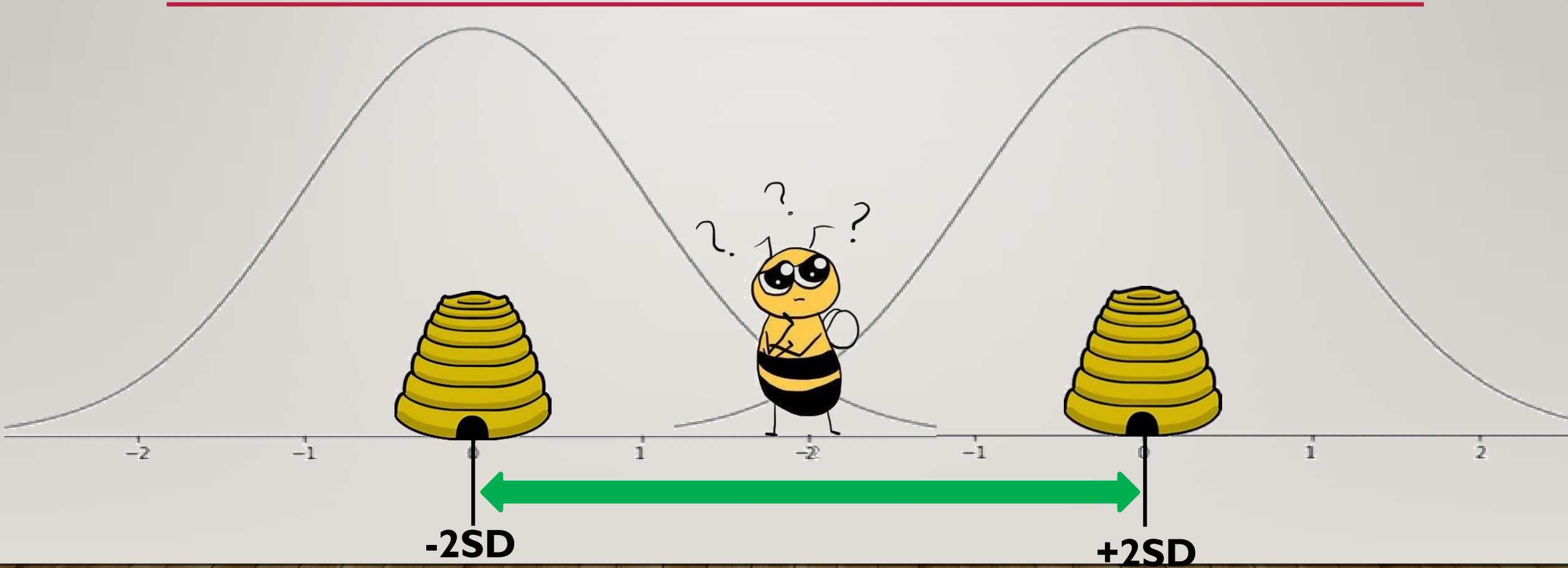












Uncertainty Calculation Methods

- **Bottom-up:**

- Determining **different sources** of uncertainty
- Establishing a **mathematical model**
- Estimating **partial uncertainties**
- Combining under the established model

- **Top-down:**

Experimental evaluation of uncertainty in the final outcome



Which Method?



- **Bottom-up:**

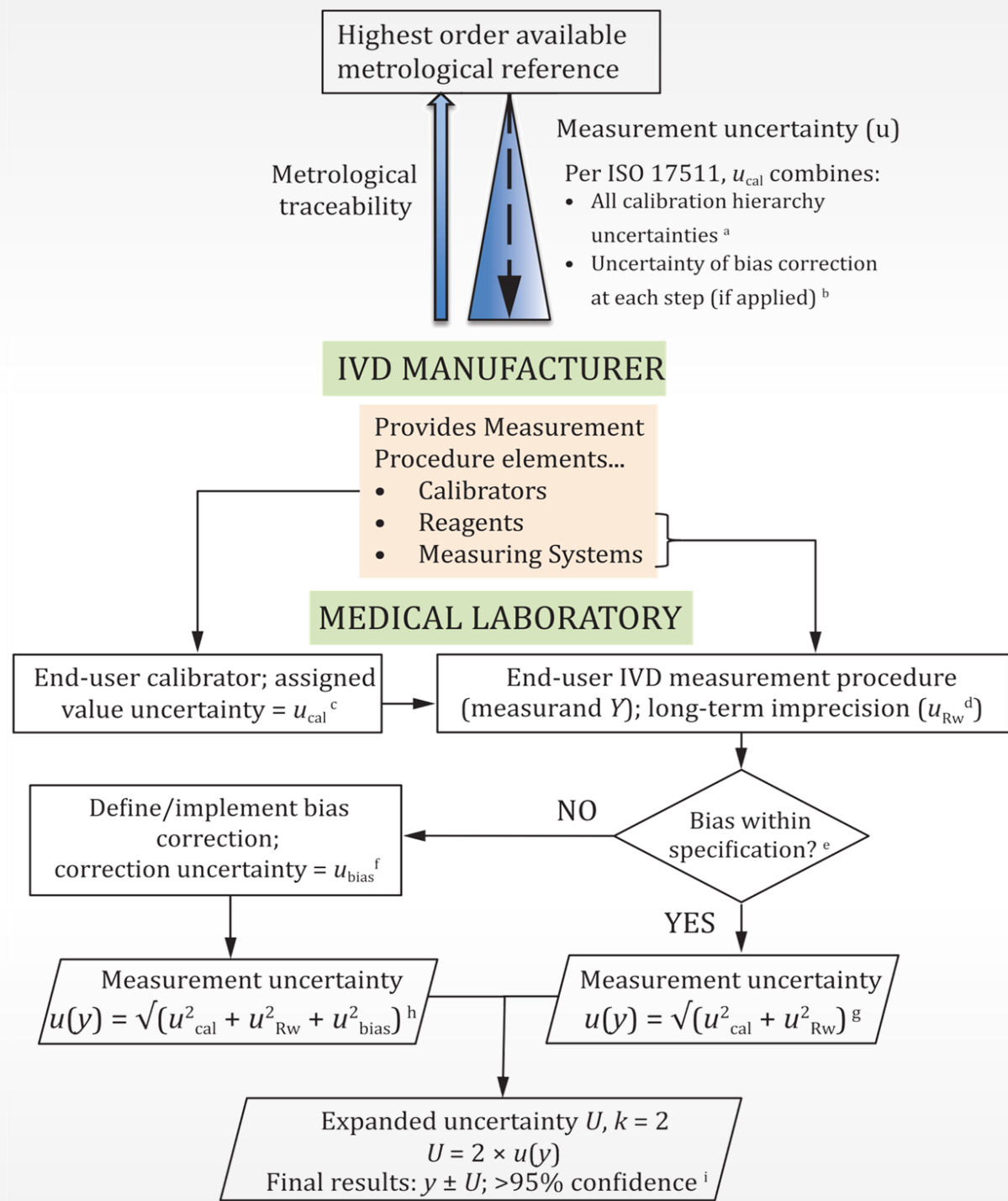
- Usually employed by **reference laboratories** to obtain ISO 17025 and 15195 certificate
- The application in medical laboratories is **too complicated** and has encountered many practical problems and objections.

- **Top-down:**

- Simpler and represents a **good alternative** to the previous approach
- Estimates MU by using **IQC**, commercial **calibrator** information, and **bias correction**

Concept Of Uncertainty





Uncertainty Variables

1. Long-term imprecision data (**SD or CV**) obtained for IQC, u_{Rw}
2. Uncertainty of end-user **calibrator** values, u_{cal}
3. Uncertainty of bias, u_{bias}

Challenges Of Uncertainty Calculation

- u_{RW}
- Changing LOT of IQC
- Changing LOT of reagents
- u_{cal} : Values for u_{cal} should be obtainable on request from IVD
- u_{bias} : Some national regulations may prohibit bias correction.

If multiple IQC levels are used, U must be calculated separately for each level.

State Of Uncertainty

Optimum **MU<0.25 I(%)**

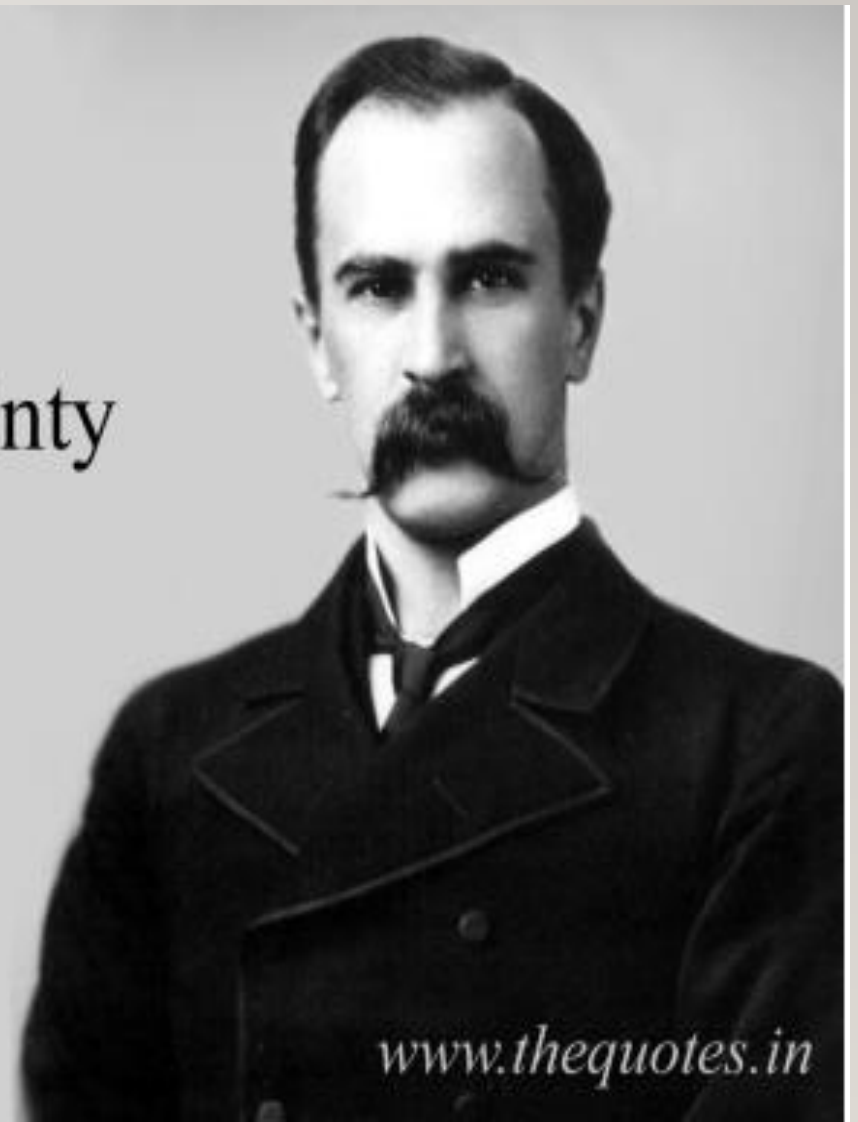
Desirable **MU<0.5 I(%)**

Minimum **MU<0.75 I(%)**



Medicine is a science of uncertainty
and an art of probability.

William Osler



www.thequotes.in