# Can antibody immunoassays, and specifically Rubella IgG assays, be claimed as quantitative?

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# Can antibody immunoassays be claimed as '*quantitative*'?

- Comparability among same patient results from different labs, methods and times should have been the driving reason for pretending 'quantitative' antibody assays in I.D. serology and, specifically, anti Rubella Ig(G) assays' calibration against the WHO Rubella reference preparation.
- Immunosorbent assays for human antibodies yield analytical responses which at least reflect:
  - unknown combinations of concentration and avidity of the analyte in the given sample
  - actual (known?) representation/viability/activity of the chosen antigenic reagent
- Different strategies for reducing time-to-result and other design constraints may cause automated immunoassay to differ significantly in reaction kinetics, thus potentially leading to different antibody selection/recognition.
- Calibration manoeuvres aimed at maximizing agreement around the proposed 'immunity cut off' (whatever the meaning of it might be) may cause inter-methods misalignments along the expected dynamic range of antibody response.

# Given the above, we believe that…

1. Quantitative claims for antibody assays should be better defined beyond generic statements of standardization against the WHO reference preparation, which cannot and does not validate any individual patient result.
2. Limits of comparability among same patient's antibody loads (even if expressed in 'IU/mL') from different labs, methods and times should be properly demonstrated or disclaimed.
3. 'Immunity' cut off limits should be more carefully proposed/understood/adopted since:
   - They generally fall within the distribution of specifically reactive antibody population .
   - They may vary among different patient populations: naturally infected, vaccinated etc.
4. The proposal: stop pretending too much from antibody quantitation in I.D. serology; leave to clinically defined 'consensus' panel (20+ samples) from individual patients the role of validating accuracy and reproducibility of classification.

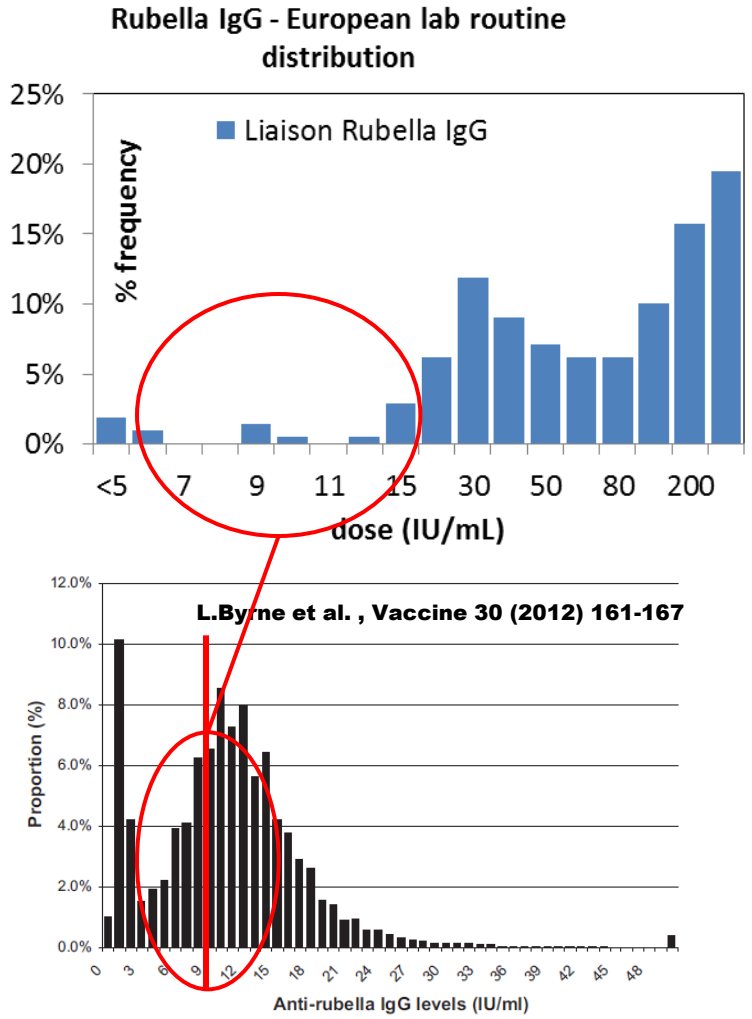


**Fig. 1.** Distribution of anti-rubella IgG levels among antenatal samples referred for confirmatory testing: 01/08/2006–31/12/2009.