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Automated lateral flow immunoassay based on upconverting nanoparticles for serological point-of-care diagnosis of pertussis

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BACKGROUND

- **Rapid quantitative** serological point-of-care determination of pertussis is essential for optimal patient management.
- Here, we developed an automated platform for Upcon® immunoassay (UIA) for quantitative serological diagnosis of pertussis (**Figure 1**).

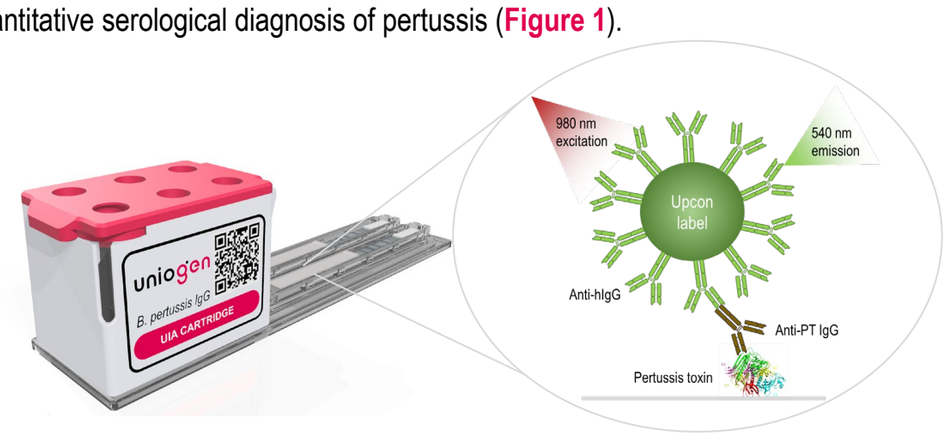

Figure 1. The B. pertussis Upcon® immunoassay is performed in a cartridge. *The assay detects anti-pertussis toxin antibodies using an anti-human-labeled luminescent Upcon particle. This particle generates upconverting luminescence, which minimizes background interference from the sample and enables highly sensitive quantitative measurements.*

MATERIALS AND METHODS

- The *B. pertussis* UIA assay was compared to the average of two standardized reference ELISA assays with a patient sample panel and separately tested with the NIBSC antiserum (human) panel 18/146 with known concentrations.
- The serum samples were tested for pertussis toxin IgG antibodies using the automated UIA assay.
- The serum samples (n=62) were diluted in 1:125 and administered into a cartridge with two parallel strips for automatic analysis using a point-of-care system under development.
- A dilution series of the First WHO International Standard (Pertussis Antiserum (Human) 1st IS;06/140) was used to calibrate the UIA assay. The results were compared to the average concentrations produced by two standardized ELISA anti-PT IgG assays.

RESULTS

- The *B. pertussis* UIA assay demonstrated excellent sensitivity and dynamic range (**Figure 2A**):
  - Limit of detection: **2 IU/mL**
  - Lower limit of quantitation: **20 IU/mL**
  - Upper limit of quantitation: **250 UI/mL**
  - Accuracy: **±20%**
  - Precision: **20%** (conc-CV%)
- The *B. pertussis* UIA assay demonstrated a good correlation with reference assays in a panel of patient samples (**Figure 2B, 2C**). Correlation between the two reference ELISAs was comparable to the correlation of the UIA assay (**Figure 2D**).

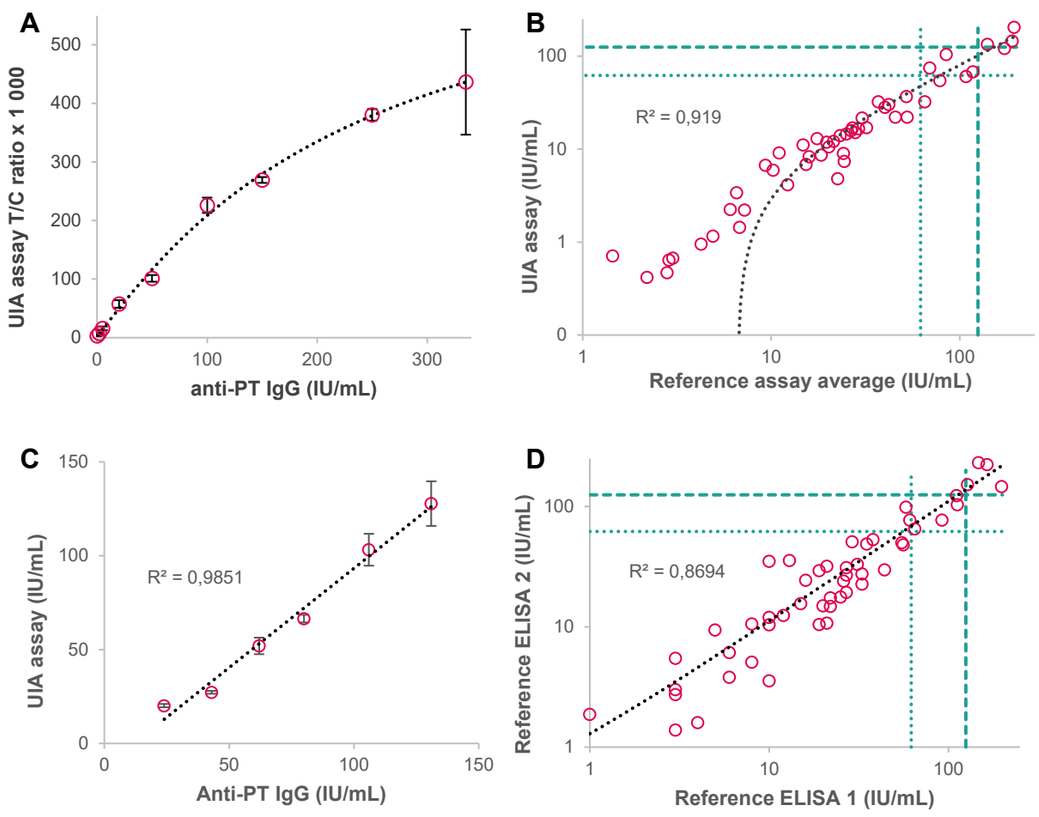

Figure 2. Evaluation of the B. pertussis UIA assay.
(A) The UIA assay demonstrated excellent sensitivity and dynamic range with a standard series of the WHO international standard.
(B) The UIA assay showed strong correlation with the average concentrations obtained from two reference ELISAs using a panel of patient samples.
(C) The UIA assay also correlated well with the NIBSC 18/146 panel sample with known concentrations.
(D) The two reference ELISAs exhibited a correlation comparable to that of the UIA assay (Figure 2B).

CONCLUSIONS

- The unique automated lateral flow assay offers a new option for rapid, quantitative and simple serological diagnosis of pertussis.
- Short turnaround time:
  - Time-to-result: **20 minutes**
  - Hands-on-time: **< 3 minutes**
  - Assay run time: **17 minutes** (in comparison to hours in ELISA)
- Excellent sensitivity due to Uniogen's proprietary Upcon labelling technology combined with platform's walk-away automation and fast turnaround time make the *B. pertussis* UIA assay ideally suited for point-of-care diagnostics.
- The platform also allows straightforward multiplexing from a single sample, e.g. simultaneous quantification of *B. pertussis* IgG and IgA serology.

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