

# VacciGel™ ELISA for direct identification and quantitation of vaccines formulated in Alum

*VacciGel™ series ELISAs are an innovative and industry's first test for the direct identification and measurement of vaccine components adsorbed on Alum adjuvants. The proprietary methods require NO ANTIGEN ELUTION or harsh treatment of the Alum gel. The assay can be completed in ~2 hrs at room temp. VacciGel™ series is available for Hepatitis B, Diphtheria, Tetanus, Pertussis, Rabies, and HCG (anti-fertility) vaccines.*

Currently, the only adjuvants approved for human vaccine are aluminum containing compounds, including aluminum hydroxide (Al(OH)<sub>3</sub>) or Alhydrogel®, aluminum phosphate (AlPO<sub>4</sub>), and potassium aluminum sulfate (KAl(SO<sub>4</sub>)<sub>2</sub>·12H<sub>2</sub>O) or alum. To ensure vaccine quality, regulatory authorities require the manufacturer to measure vaccine content in the final product. World Health Organization (WHO) recommends that at least 80% of the tetanus vaccine be adsorbed to the gel. In particular, it is essential to determine the amount as well as the identity and integrity of the antigens bound to aluminum containing adjuvants following formulation. Aluminum-based gels are typically fibrous or beaded in suspension. The presence of aggregates, turbidity, flocculent gels or beads in solution prevents direct quantitation of protein content in formulations using assays such as Lowry, BCA, or Bradford protein assay, not to mention that these assays are all non-specific and low in sensitivity. Alhydrogel formulations also do not allow complete dissolution or extraction making it very difficult to know the identity of the vaccines or know the amount of the protein after their dispensing. There have been occasions when Tetanus vaccine has been mislabeled, intentionally or unintentionally, with the HCG-vaccine (anti-fertility). Therefore, there is an urgent need for an assay that can quickly identify and measure the vaccine contents without any extraction or dissolution.

The US licensed vaccines that contain aluminum adjuvants are:

### Hepatitis B vaccines (monovalent or multivalent):

Merck vaccines: Comvax (HepB/Hib), Recombivax HB (Hep B), PedvaxHib (Hib-PRP-OMP)

GlaxoSmithKline vaccines- Enderix-BPED/Adol (HepB Ped/Adol), Enderix-B for adults (HepB), Pediarix (DTAP/HepB/IPV)

WyethLederle vaccines-; Trihibit (DTAP/Hib), ActHib (Hib-PRP-T) - Sanofi Pasteur; HibTiter (Hib-Hboc)

### DTP (diphtheria-tetanus-pertussis vaccine)

**GlaxoSmithKline**-Pediarix (DTAP/HepB/IPV), Infanrix (DTAP), Boostrix (Tetanus, Diphtheria, Acellular Pertussis – **Sanofi Pasteur**-Trihibit (DTAP/Hib), Daptacel (DTAP), Tripedia (DTAP),Td (Adult)- Adacel (tetanus, Diphtheria, Acellular Pertussis), Decavac™ (tetanus/Diphtheria)  
**Aventis Pasteur**-DT (Pediatric)

### Tetanus vaccines (monovalent or multivalent):

**GlaxoSmithKline**-Pediarix (DTAP/HepB/IPV), Infanrix (DTAP), Boostrix (Tetanus, Diphtheria, Acellular Pertussis **Sanofi Pasteur**-Trihibit (DTAP/Hib), Daptacel (DTAP), Tripedia (DTAP),Td (Adult)- Adacel (tetanus, Diphtheria, Acellular Pertussis), Decavac™ (tetanus/Diphtheria)  
**Aventis Pasteur**-DT (Pediatric)

### Pertussis vaccines (monovalent or multivalent):

**GlaxoSmithKline**-Pediarix (DTAP/HepB/IPV), Infanrix (DTAP), Boostrix (Tetanus, Diphtheria, Acellular Pertussis – **Sanofi Pasteur**-Trihibit (DTAP/Hib), Daptacel (DTAP), Tripedia (DTAP),Td (Adult)- Adacel (tetanus, Diphtheria, Acellular Pertussis), Decavac™ (tetanus/Diphtheria)  
**Aventis Pasteur**-DT (Pediatric)

### Human Papillomavirus (HPV) vaccine Anthrax, vaccine; Rabies vaccine



- What are these vaccines?
- Is this Tetanus or anti-fertility vaccine?
- Are the vaccines still potent and have the expected vaccine contents?

**Identify and measure the vaccines formulated in gels with VacciGel™ ELISAs**

### VacciGel™ Direct ELISA Features

- Direct testing of vaccines formulated in Aluminum gels (Alhydrogel, Adjuphos or Alum)
- High sensitivity ELISA allow testing at 1:100-1:500 diluted vaccines
- No complicated protocol, instruments or extraction procedure that may destroy the vaccines
- Room temp assay in < 2 hrs. Stability ~12 months
- Sensitivity (1-5 ng of vaccine components)
- Use **VacciGel™** ELISA for routine manufacturing, Vaccine identification, and antigen dose at the time of manufacture and lot testing; Shelf life etc.
- **VacciGel™** ELISA available for Hepatitis B, Diphtheria, Tetanus, Pertussis, Rabies, and HCG (anti-fertility) vaccines
- **All kits are quantitative and supplied in 50 tests/pk.**

This kit for in vitro research use only.

Vaccine antigens	Catalog#	Product Description
Diphtheria Toxin/toxoid	VAC-DTX-50	VacciGel Direct ELISA for the measurement of Diphtheria Toxoid in Vaccines formulated in Alum
HbSAg	VAC-HBS-50	VacciGel Direct ELISA for the measurement of Hepatitis B Vaccine (HBsAg) formulated in Alum
Human HCG	VAC-HCG-50	VacciGel Direct ELISA for the measurement of HCG (contamination) in Vaccines formulated in Alum
Anthrax PA83	VAC-P83-50	VacciGel Anthrax Protective Antigen 83 (PA83) Protein Adsorbed on Alum, ELISA kit for 50 tests
B. Pertussis Toxin/toxoid	VAC-PTX-50	VacciGel Direct ELISA for the measurement of Pertussis Toxoid in Vaccines formulated in Alum
Tetanus	VAC-TTX-50	VacciGel Direct ELISA for the measurement of Tetanus Toxoid in Vaccines formulated in Alum

Vaccigel\_Direct\_ELISA\_Flr 160611A

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