

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)₃) or Alhydrogel®, aluminum phosphate (AlPO₄), and potassium aluminum sulfate (KAl(SO₄)₂·12H₂O) 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: DTP (diphtheria-tetanus-pertussis vaccine), DTaP (diphtheria-tetanus-acellular pertussis vaccine); Some but not all Hib (Haemophilus influenzae type b) conjugate vaccines; Pneumococcal conjugate vaccine; Hepatitis B vaccines, All combination DTaP, Tdap, Hib, or Hepatitis B vaccines, Hepatitis A vaccines; 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?

Find out with VacciGel™ ELISAs to identify and measure the vaccine formulated in gels

VacciGel™ Direct ELISA Features

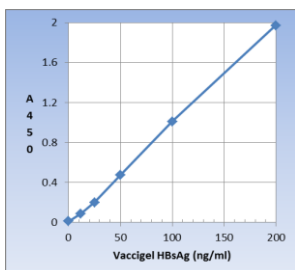
- Direct testing of vaccines formulated in Aluminum gels (Alhydrogels, Adjuphos or Alum)
- High sensitivity ELISA allow testing at 1:100-1:500 diluted vaccines
- No complicated protocol, instruments or extraction procedure that may destroy the vaccines
- Room temp assay in < 2 hrs. Stability ~12 months
- 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

This kit For in vitro research use only.

VacciGel™ direct ELISA for the detection and measurement of Hepatitis B vaccine (HBsAg) adsorbed onto the Alhydrogel, Cat #VAC-HBS-50 (50 Tests)



Merck Recombivax
HBsAg @ 10 µg/ml



HBsAg in Alhydrogel (ng/ml)

VacciGel™ Direct ELISA for Hepatitis B Vaccine #VAC-HBS-50

- Standards: Recombinant HBsAg adsorbed on Alhydrogel (Aluminum hydroxide); 12.5-200 ng/ml
- Standards calibrated to Merck Recombivax
- Vaccine sample: 100 ul (1:100-1:500 diluted)
- Assay Time: 105 min at room temp (3 incubations)
- Sensitivity: HBsAg ~5 ng/ml vaccine
- Standard vaccine contains HBsAg @ =10 µg/ml or 10,000 ng/ml.

Suitable for 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)

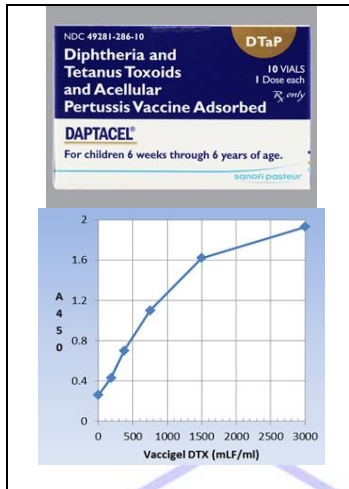
WyethLederle vaccines-; Trihibit (DTAP/Hib), ActHib (Hib-PRP-T) - Sanofi Pasteur; HibTiter (Hib-Hboc)

India Contact:

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VacciGel™ direct ELISA for the detection and measurement of Diphtheria Vaccine (Diphtheria Toxoid adsorbed onto the Adjuphos gel, Cat #VAC-DTX-50 (50 tests)



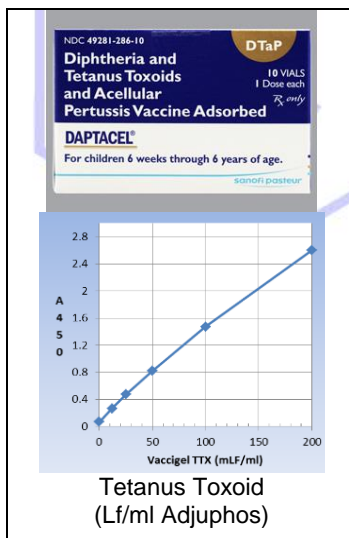
VacciGel™ Direct ELISA for Diphtheria Vaccine #VAC-DTX-50

- Standards: DTX adsorbed on Adjuphos gel (Al. phosphate AIPO₄); 175-3000 mLf/ml
- Standards calibrated to Sanofi Triple vaccine Daptacel
- Vaccine sample: 100 ul (1:100-1:500 diluted)
- Assay Time: 105 min at room temp (3 incubations)
- Sensitivity: Diphtheria Toxoid ~75 mL/ml vaccine (standard vaccine)**
- Standard Daptacel vaccine contains Diphtheria Toxoid @ =30,000 mLf/ml**

Suitable for Diphtheria 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)

VacciGel™ direct ELISA for the detection and measurement of Tetanus Vaccine (Tetanus Toxoid adsorbed onto the Adjuphos gel, Cat #VAC-TTX-50 (50 Tests)



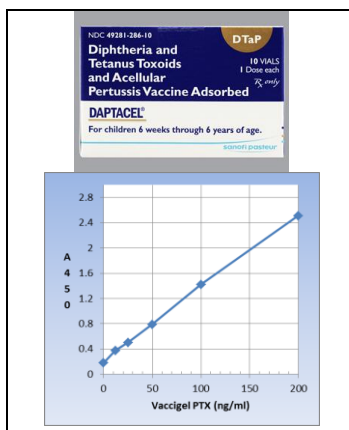
VacciGel™ Direct ELISA for Tetanus Vaccine #VAC-TTX-50

- Standards: Tetanus Toxoid adsorbed on Adjuphos gel (Aluminum phosphate AIPO₄); 0.6.25-100 mLf/ml
- Standards calibrated to Sanofi Triple vaccine Daptacel
- Vaccine sample: 100 ul (1:100-1:500 diluted)
- Assay Time: 105 min at room temp (3 incubations)
- Sensitivity: Tetanus Toxoid ~3 mLf/ml vaccine**
- Standard Daptacel vaccine contains TTX @ =10 Lf/ml or 10,000 mLf/ml.**

Suitable for 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)

VacciGel™ direct ELISA for the detection and measurement of Pertussis Vaccine (Pertussis Toxoid adsorbed onto the Adjuphos gel, Cat #VAC-PTX-50 (50 Tests)



VacciGel™ Direct ELISA for Pertussis Vaccine #VAC-PTX-50

- Standards: Tetanus Toxoid adsorbed on Adjuphos gel (Aluminum phosphate AIPO₄); 12.5-200 ng/ml
- Standards calibrated to Sanofi Triple vaccine Daptacel
- Vaccine sample: 100 ul (1:100-1:500 diluted)
- Assay Time: 105 min at room temp (3 incubations)
- Sensitivity: Pertussis Toxoid ~5 ng/ml vaccine**

Suitable for 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)

Vaccigel_Direct_ELISA_Flr 13111A

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