

agriQ Quest Ltd

**Presentation to Joint Committee of
Experts on Tetanus Toxoid Vaccine
Testing
23rd January 2015**

Background

- The Ministry of Health and Catholic Health Commission established a joint committee to investigate the safety of the tetanus toxoid vaccine administered in the last Kenyan vaccination campaigns
- agriQ Quest Ltd was appointed by the joint committee of experts to carry out analysis on selected vials of the tetanus toxoid vaccines

Objective of the Assessment

- Analyze content of the vials sampled for the presence of beta human chorionic gonadotropin hormone (β hCG)
- Quantify the levels of (β hCG) for each of the samples where present
- Full toxicological analysis of the vaccine, identify any other substances present, apart from the immunogen, detoxicant and diluents
- Production of a written report - to include procedure for analysis, relevant references applied to the analysis, citing publications
- To inform and interpret to the joint committee of experts the findings from the Laboratory analysis

Execution of the Assessment

- Sampling and Sample Submission

- Lot 1 - 10th Dec. 2014 at KEPI - 14 samples collected
- Lot 2 - 17th Dec. 2014 at Upper Hill Medical Center - 4 samples collected
- Lot 3 - Matching samples submitted to Laboratory - 40 samples



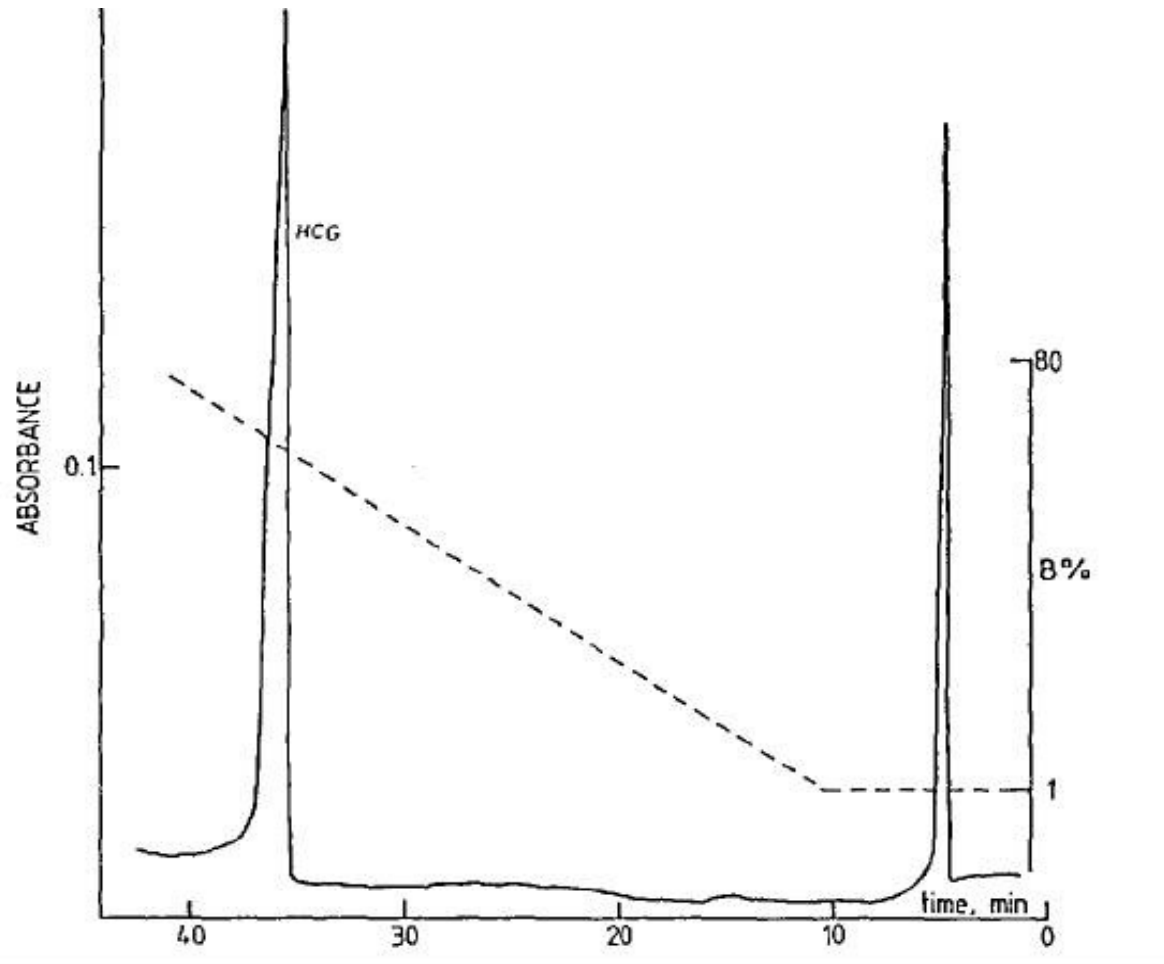
Objective of the Assessment

- Further instructions from the Pharmacy and Poisons Board on 17th Dec. 2014 directed the Laboratory to restrict its initial investigation to:
 - Determining if (β hCG) was present in the submitted vials
 - Quantity of (β hCG) present in each of the vials tested [this objective later abandoned].

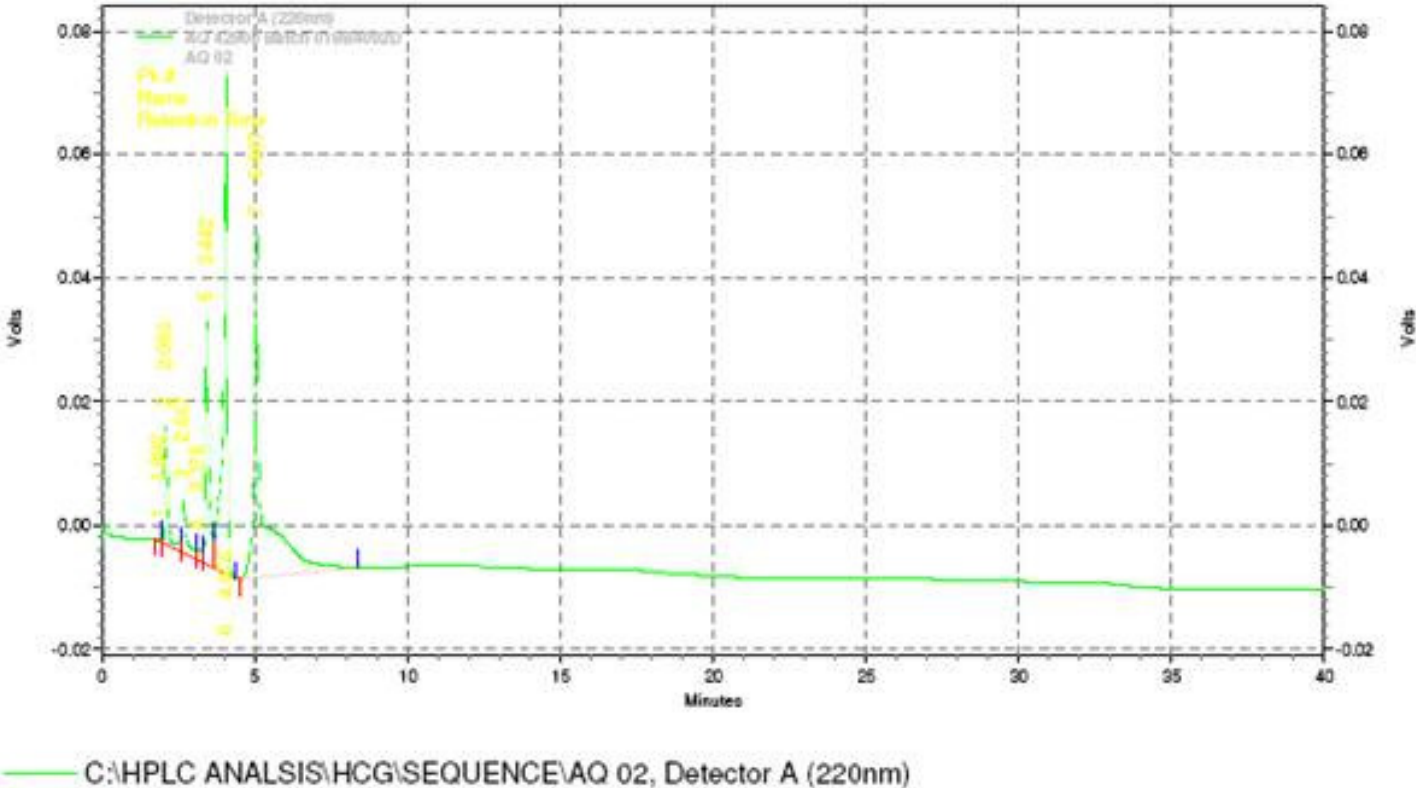
Analysis Method and Equipment

- Equipment
 - Shimadzu Class VP 10 HPLC equipment
- Method
 - Rapid isolation of hCG using anion exchange chromatography
 - Retention time for the hCG peak - 35mins

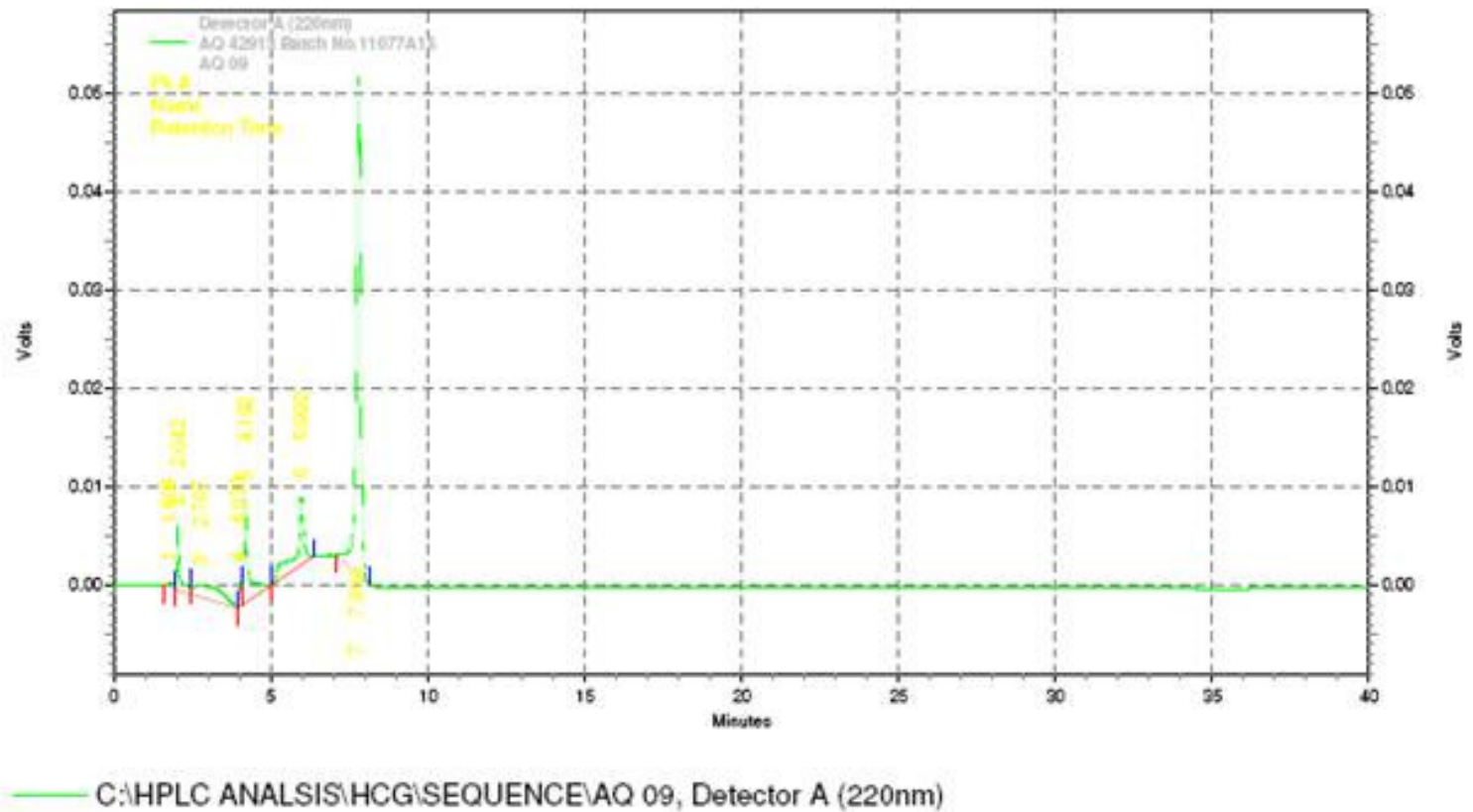
Typical hCG Chromatogram



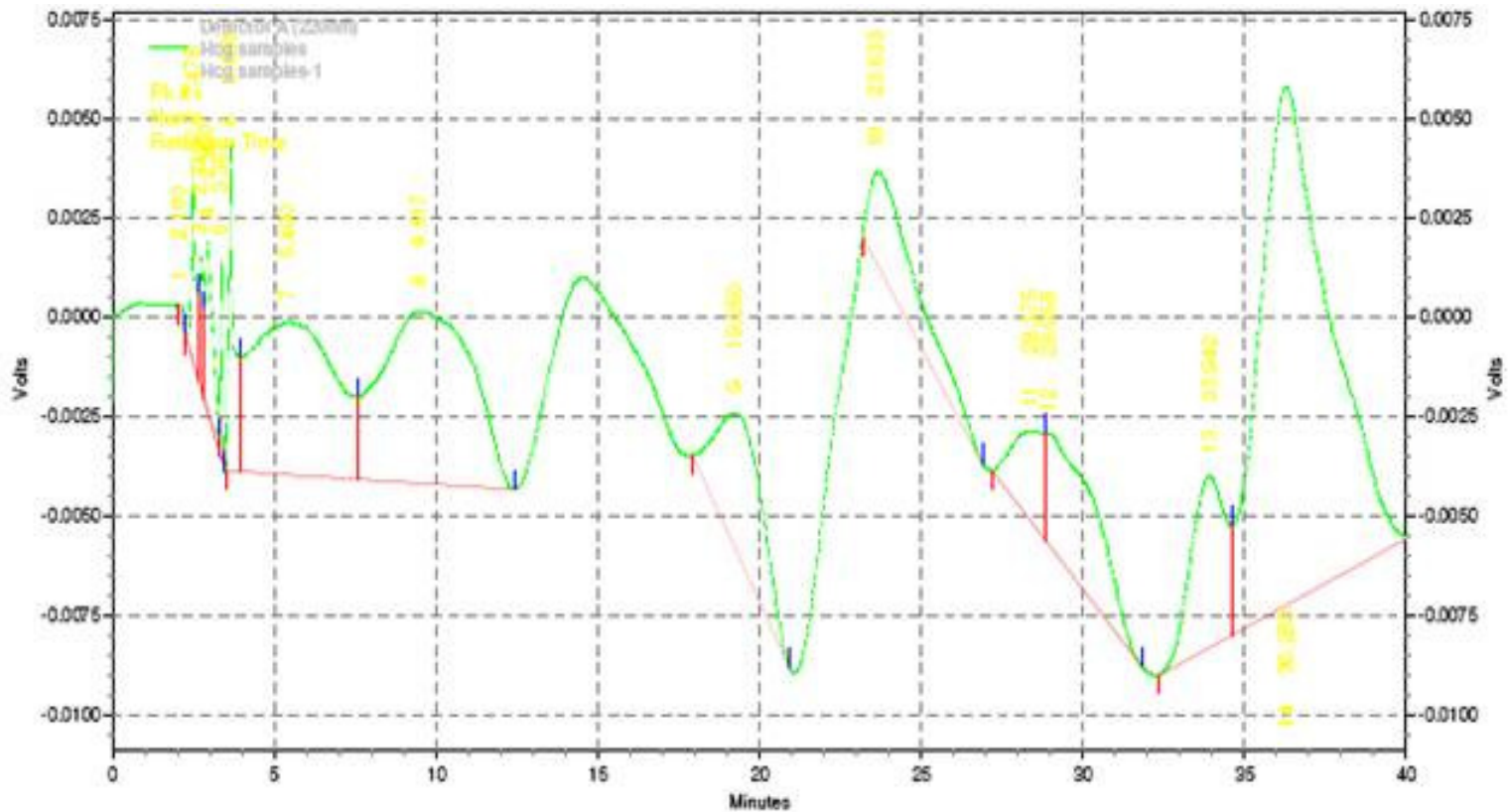
Laboratory Results - TT vaccine AQ 42905



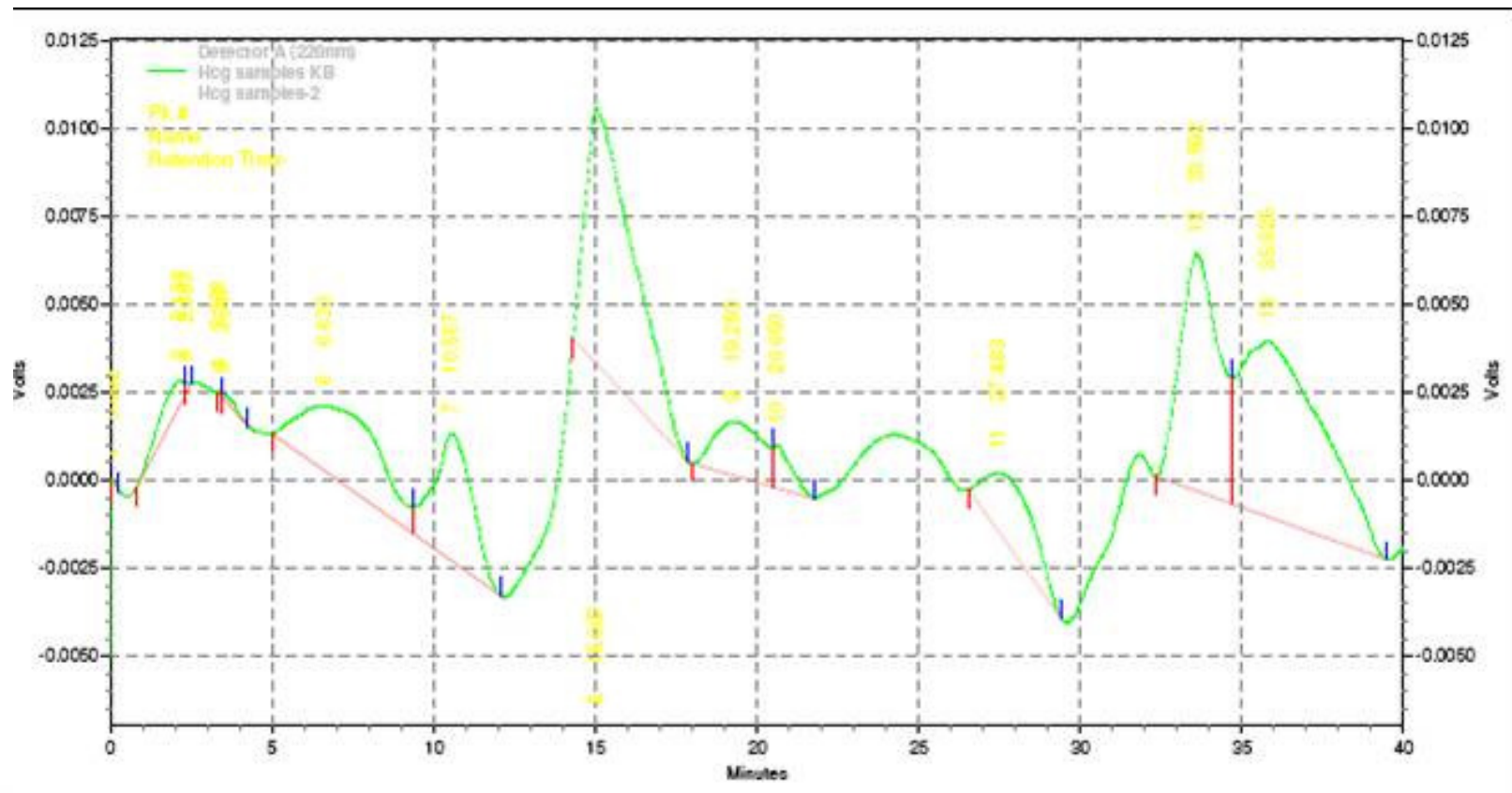
Laboratory Results - TT Vaccine AQ 42906



Laboratory Results - TT Vaccine AQ 42915

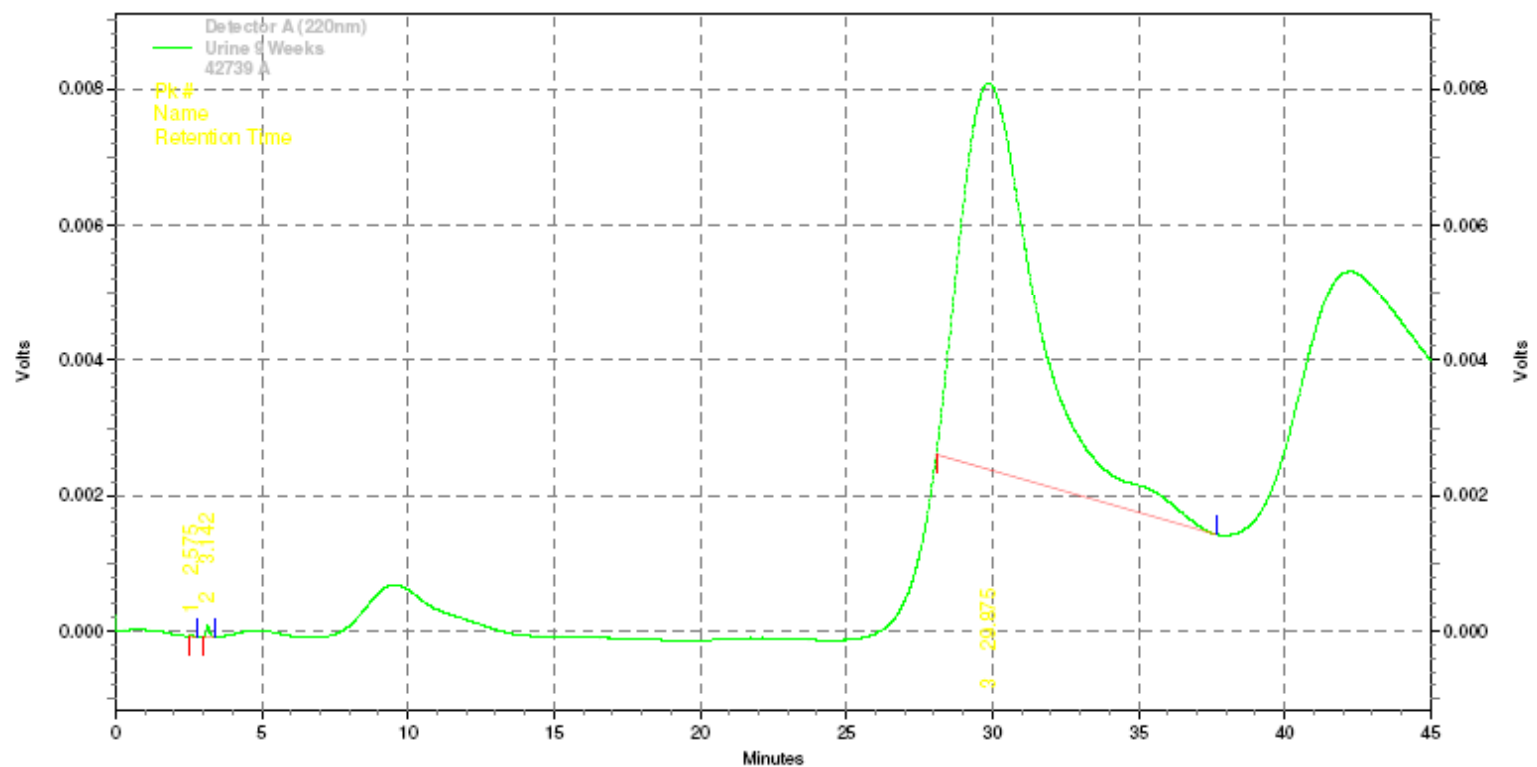


Laboratory Results - TT Vaccine AQ 42916



Laboratory Results - Calibration Data

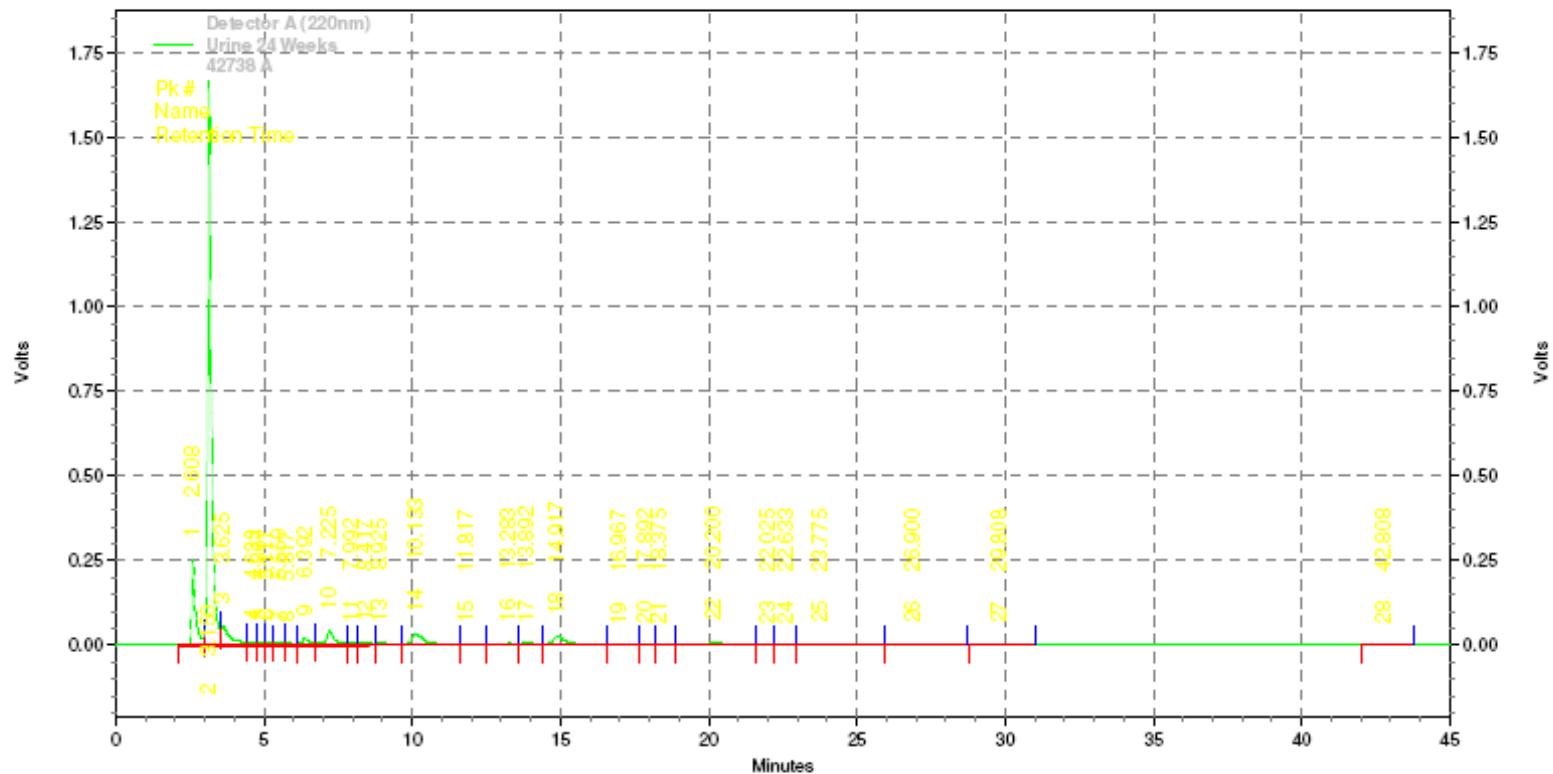
Urine 9 wks pregnancy



C:\HPLC ANALYSIS\HCG\SEQUENCE\42739 A, Detector A (220nm)

Laboratory Results - Calibration Data

Urine 24 wks pregnancy



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Conclusions from the Analysis

- Three samples of B.Nos. 019L3001B & 019L3001C found to contain β hCG
- Matching vials submitted did not contain β hCG
- β hCG present in the vials-chemically linked
- Assay for β hCG in its pure form will not produce such a chromatogram as hCG will be metabolized
- Assay for β hCG that is chemically bonded shows modification in the chromatogram